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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

Prevailing Rate Systems

CFR Correction

In Title 5 of the Code of Federal Regulations, Parts 1 to 699, revised as of January 1, 2017, on page 464, in Part 532, Subpart B, Appendix C, under MINNESOTA, Minneapolis-St. Paul, *Area of Application. Survey area plus:,* Minnesota:, the first occurrence of ''Freeborn'' is replaced with ''Fillmore''.

[FR Doc. 2017–13805 Filed 6–29–17; 8:45 am]

BILLING CODE 1301–00–D

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 709

RIN 3133–AE41

Safe Harbor

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (''Board'') is issuing this final rule to amend its regulations regarding the treatment by the Board, as liquidating agent or conservator (''liquidating agent'' or ''conservator,'' respectively) of a federally insured credit union (''FICU''), of financial assets transferred by the credit union in connection with a securitization or a participation. The final rule replaces NCUA's current safe harbor for financial assets transferred in connection with securitizations and participations in which the financial assets were transferred in compliance with the existing regulation, and defines the conditions for safe harbor protection for securitizations and participations for which transfers of financial assets would be made after the effective date of this rule.

DATES: The effective date for this rule is July 31, 2017.

FOR FURTHER INFORMATION CONTACT: John Nilles, Senior Capital Markets Specialist, Office of Examination and Insurance, at (703) 518–1174; or John H. Brolin, Senior Staff Attorney, Office of General Counsel, at (703) 518–6438; National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Background

In 2000, when it adopted a regulation codified at 12 CFR 709.10,[1] the Board clarified the scope of its statutory authority as conservator or liquidating agent to disaffirm or repudiate contracts of an FICU with respect to transfers of financial assets by a FICU in connection with a securitization or participation. Current § 709.10 provides that a conservator or liquidating agent will not use its statutory authority to disaffirm or repudiate contracts to reclaim, recover, or recharacterize as property of a FICU or the liquidation estate any financial assets transferred by the FICU in connection with a securitization or in the form of a participation, provided that such transfer meets all conditions for sale accounting treatment under generally accepted accounting principles (''GAAP'').[2] Current § 709.10 also provides a ''safe harbor'' by confirming ''legal isolation'' if all other standards for off balance sheet accounting treatment, along with some additional conditions focusing on the enforceability of the transaction, were met by the transfer in connection with a securitization or a participation. Satisfaction of ''legal isolation'' is vital to securitization transactions because of the risk that the pool of financial assets transferred into the securitization trust could be recovered in bankruptcy or in a credit union liquidation. Generally, to satisfy the legal isolation condition, the transferred financial assets must have been presumptively placed beyond the reach of the transferor, its creditors, a bankruptcy trustee, or in the case of a FICU, NCUA as conservator or liquidating agent. Thus, current § 709.10 addresses only purported sales which meet the conditions for off balance sheet accounting treatment under GAAP. The implementation of accounting rules since 2000, however, has created uncertainty for loan participation and potential securitization participants.

A. Modifications to GAAP Accounting Standards

In 2009, the Financial Accounting Standards Board (''FASB'') finalized modifications to GAAP through Statement of Financial Accounting Standards No. 166, (now codified in FASB Accounting Standards Codification (ASC) Topic 860, Transfers and Servicing) and Statement of Financial Accounting Standards No. 167 (now codified in FASB ASC Topic 810, Consolidation) (together, the ''2009 GAAP Modifications''). The 2009 GAAP Modifications made changes that affect whether a special purpose entity (''SPE'') must be consolidated for financial reporting purposes, thereby subjecting many SPEs to GAAP consolidation requirements. These accounting changes could require a FICU to consolidate an issuing entity to which financial assets have been transferred for securitization on to its balance sheet for financial reporting purposes primarily because an affiliate of the FICU retains control over the financial assets. Given the 2009 GAAP Modifications, legal and accounting treatment of a transaction may no longer be aligned. As a result, the safe harbor provision of the 2000 Rule may not apply to a transfer in connection with a securitization that does not qualify for off balance sheet accounting treatment.

FASB ASC Topic 860 also affects the treatment of participation interests transferred by a FICU, in that it defines participating interests as pari-passu, pro-rata interests in financial assets, and subjects the sale of a participation interest to the same conditions as the sale of financial assets. FASB ASC Topic 860 provides that transfers of

[1] 65 FR 55442 (Sept. 14, 2000).

[2] In the Proposal, NCUA stated that the agency had not previously stated that federal credit unions (''FCUs'') have the authority to issue asset-backed securities (''ABS'') and that its understanding was that no FCU had done so. NCUA also does not believe that any federally insured, state-chartered credit unions (''FISCUs'') have issued ABS. Therefore, the securitization aspect of the 2000 Rule has not been applied. In connection with this final rule updating the 2000 Rule, the Office of General Counsel recently published a legal opinion letter on NCUA's Web site, which finds that the securitization of assets is a power incidental to the operation of FCUs. Accordingly, if an FCU (or a FISCU if permitted by state law) issues ABS, these amendments to § 709.10 are necessary to preserve the safe harbor for investors.

participation interests that do not qualify for sale treatment will be viewed as secured borrowings. While the GAAP modifications have some effect on participations, most participations are likely to continue to meet the conditions for sale accounting treatment under GAAP.

B. FCU Act Changes

In 2005, Congress enacted Section 207(c)(13)(C)[3] of the Federal Credit Union Act (the ''FCU Act'').[4] This paragraph generally provides that no person may exercise any right or power to terminate, accelerate, or declare a default under a contract to which the FCU is a party, or obtain possession of or exercise control over any property of the FCU, or affect any contractual rights of the FCU, without the consent of the conservator or liquidating agent, as appropriate, during the 45-day period beginning on the date of the appointment of the conservator or the 90-day period beginning on the date of the appointment of the liquidating agent. If a securitization is treated as a secured borrowing, section 207(c)(13)(C) could prevent the investors from recovering monies due to them for up to 90 days. Consequently, securitized assets that remain property of the FCU (but subject to a security interest) would be subject to the stay, raising concerns that any attempt by securitization investors to exercise remedies with respect to the FCU's assets could be delayed. During the stay, interest and principal on the securitized debt could remain unpaid. This 90-day delay could cause substantial downgrades in the ratings provided on existing securitizations and could prevent planned securitizations for multiple asset classes, such as credit cards, automobile loans, and other credits, from being brought to market.

C. Notice of Proposed Rulemaking

In response to the changes outlined above, on June 26, 2014, the Board issued a notice of proposed rulemaking (Proposal) to revise the agency's safe harbor provisions.[5] The Proposal was prompted in part by the Federal Deposit Insurance Corporation's (FDIC's) decision in 2010 to issue a final rule to resolve the issues raised by the 2009 GAAP modifications and parallel 2005 changes to the Federal Deposit Insurance Act.[6] To avoid unnecessary complexity and assure loan participants and securitization investors, the Proposal was modeled on the FDIC's safe harbor rule, which is codified at 12 CFR 360.6, Treatment of Financial Assets Transferred in Connection with a Securitization or Participation.

The Proposal sought to address concerns of securitization investors and loan participants regarding the impact of the 2009 GAAP Modifications on the eligibility of transfers of financial assets for safe harbor protection by clarifying the position of the conservator or liquidating agent under established law. Under section 207(c)(12) of the FCU Act, the conservator or liquidating agent cannot use its statutory power to repudiate or disaffirm contracts to avoid a legally enforceable and perfected security interest in transferred financial assets ''except where such an interest is taken in contemplation of the credit union's insolvency or with the intent to hinder, delay or defraud the credit union or the creditors of such credit union.''[7] This provision applies whether or not a securitization or participation transaction meets the conditions for sale accounting. The Proposal sought to clarify that, prior to any monetary default or repudiation, the conservator or liquidating agent would consent to the making of required payments of principal and interest and other amounts due on the securitized obligations during the statutory stay period.

In addition, the Proposal stated that, if the conservator or liquidating agent decides to repudiate the securitization transaction, the payment of repudiation damages in an amount equal to the par value of the outstanding obligations on the date of liquidation will discharge the lien on the securitization assets.

Following issuance of NCUA's Proposal, the FDIC issued two additional rules revising its securitization safe harbor rule to (1) be consistent with regulations required under Section 15G of the Securities and Exchange Act, 15 U.S.C. 78a *et seq.* pursuant to section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act;[8] and (2) clarify that the documents governing a securitization transaction need not require an action prohibited under Regulation X (12 CFR part 1024).[9] The Board has reviewed these changes and believes they are within the scope of the Proposal; consistent with current accepted standards and practices within the securitization industry; and uncontroversial enough in nature so that the public would not reasonably benefit from being given an additional opportunity to provide comments on these minor changes. Accordingly, the Board has amended the original proposed language to incorporate those conforming amendments into § 709.10(b)(5)(i) and (b)(3)(ii)(A) of this final rule. The amendments are discussed in more detail below.

II. Comments on the Proposal

NCUA received seven comments on the Proposal to continue the safe harbor for financial assets transferred in connection with securitizations and participations in which the financial assets transferred in connection with the securitization. All the commenters supported the Proposal, stating that investors would have no interest in pursuing securitizations without the safe harbor protections. Two commenters, however, did question the proposed limit of six tranches in a securitization. One commenter also questioned the proposed limits on external credit enhancements. These comments are discussed in more detail below. Based on the rationale previously set forth, the commenters overwhelming support, and for the reasons explained in more detail below, the Board has decided to finalize the Proposal with only the slight modification mentioned above to § 709.10(b)(5)(i).

III. Final Rule

A. General Considerations

Consistent with the Proposal, this final rule replaces current § 709.10 of NCUA's regulations. Section 709.10(a) of the rule sets forth definitions of terms used in the rule. It retains many of the definitions used in the current § 709.10(a), but modifies or adds definitions to the extent necessary to accurately reflect current industry practice in securitizations. Pursuant to these definitions, the safe harbor does not apply to certain government sponsored enterprises (''Specified GSEs''), affiliates of certain such enterprises, or any entity established or guaranteed by those GSEs. In addition, the rule is not intended to apply to the Government National Mortgage Association (''Ginnie Mae'') or Ginnie Mae-guaranteed securitizations. When Ginnie Mae guarantees a security, the mortgages backing the security are assigned to Ginnie Mae, an entity owned entirely by the United States government. Ginnie Mae's statute contains broad authority to enforce its contract with the lender/issuer and its ownership rights in the mortgages backing Ginnie Mae-guaranteed

[3] 12 U.S.C. 1787(c)(13)(C).

[4] 12 U.S.C. 1751 *et seq.*

[5] 79 FR 36252 (June 26, 2014).

[6] 75 FR 60287 (Sept. 30, 2010).

[7] 12 U.S.C. 1787(c)(12).

[8] 80 FR 73087 (Nov. 24, 2015).

[9] 81 FR 41422 (June 27, 2016).

securities. In the event that an entity otherwise subject to the rule issues both guaranteed and non-guaranteed securitizations, the securitizations guaranteed by a Specified GSE are not subject to the rule.

Section 709.10(b) of this final rule imposes conditions to the availability of the safe harbor for transfers of financial assets to an issuing entity in connection with a securitization. These conditions make a clear distinction between the conditions imposed on residential mortgage-backed securities (RMBS) from those imposed on securitizations for other asset classes. In the context of a conservatorship or liquidation, the conditions applicable to all securitizations will improve overall transparency and clarity through disclosure and documentation requirements, along with ensuring effective incentives for prudent lending by requiring that the payment of principal and interest be based primarily on the performance of the financial assets and by requiring retention of a share of the credit risk in the securitized loans.

The conditions applicable to RMBS are more detailed and include additional capital structure, disclosure, documentation and compensation requirements, as well as a requirement for the establishment of a reserve fund. These requirements are intended to address the factors that caused significant losses in RMBS securitization structures as demonstrated in the 2007–2008 financial crisis. Confidence can be restored in RMBS markets only through greater transparency and other structures that support sustainable mortgage origination practices and require increased disclosures. These standards respond to investor demands for greater transparency and alignment of the interests of parties to the securitization. In addition, they are generally consistent with industry efforts, while taking into account legislative and regulatory initiatives.

B. Capital Structure and Financial Assets

The benefits of this final rule should be available only to securitizations that are readily understood by the market, increase liquidity of the financial assets, and reduce consumer costs. Consistent with the Security and Exchange Commission's (''SEC's'') Regulation AB, the documents governing the securitization must provide financial asset level disclosure as appropriate to the securitized financial assets for any re-securitizations (securitizations supported by other securitization obligations). These disclosures must include full disclosure of the obligations, including the structure and the assets supporting each of the underlying securitization obligations, and not just the obligations that are transferred in the re-securitization. This requirement applies to all re-securitizations, including static re-securitizations as well as managed collateralized debt obligations.

All securitizations. Consistent with the Proposal, this final rule provides that securitizations that are unfunded or synthetic transactions are not eligible for expedited consent. To support sound lending, the documents governing all securitizations must require that payments of principal and interest on the obligations be primarily dependent on the performance of the financial assets supporting the securitization and that such payments not be contingent on market or credit events that are independent of the assets supporting the securitization, except for interest rate or currency mismatches between the financial assets and the obligations to investors.

RMBS only. In formulating the rule, the Board sought to permit innovation and accommodate financing needs, and thus attempted to strike a balance between permitting multi-tranche structures for RMBS transactions and promoting readily understandable securitization structures and limiting overleveraging of residential mortgage assets.

For RMBS only, the Proposal limited the capital structure of the securitization to six or fewer tranches to discourage complex and opaque structures. The most senior tranche could include time-based sequential pay or planned amortization and companion sub-tranches, which are not viewed as separate tranches for the purpose of the six tranche requirement. This condition would not have prevented an issuer from creating the economic equivalent of multiple tranches by re-securitizing one or more tranches, so long as they meet the conditions set forth in the rule, including adequate disclosure in connection with the re-securitization. In addition, RMBS could not include leveraged tranches that introduced market risks (such as leveraged super senior tranches). Although the financial assets transferred into an RMBS would have been permitted to benefit from asset level credit support, such as guarantees (including guarantees provided by governmental agencies, private companies, or government-sponsored enterprises), co-signers, or insurance, the RMBS could not benefit from external credit support at the issuing entity or pool level. The Proposal intended that guarantees permitted at the asset level include guarantees of payment or collection, but not credit default swaps or similar items. The temporary payment of principal and interest, however, could be supported by liquidity facilities. These conditions were designed to limit both the complexity and the leverage of an RMBS and therefore the systemic risks introduced by them in the market. In addition, the Proposal provided that the securitization obligations could be enhanced by credit support or guarantees provided by Specified GSEs. However, as noted in the discussion on the definitions in the Proposal, a securitization that was wholly guaranteed by a Specified GSE would not have been subject to the rule and thus would not have been eligible for the safe harbor.

Public Comments on the Proposal

Two commenters expressed concern that codifying a limit of six credit tranches in a securitization may have the unintended consequence of limiting a FCU's ability to access the market or issuing a securitization at the best possible price. The commenter recommended that, because there is no empirical evidence that structures with more than six tranches create materially more risk than those with less than six, the Board should eliminate this requirement from the safe harbor. In addition, one commenter urged elimination of the prohibition on external credit enhancements for RMBS.

Discussion

The Board disagrees with the commenter's recommendations. As previously stated, the rule was intentionally modeled on § 360.6 of the FDIC's regulations to encourage a market for securitization participants and help assure investors. The limiting language in § 709.10(b)(1)(ii)(A) and (B) of the Proposal is nearly identical [10] to the language in § 360.6(b)(1)(ii)(A) and (B) of FDIC's regulation. Retaining the six credit tranche limitation and the prohibition on external credit enhancements will not disadvantage FICUs relative to banks, and will help limit the complexity of assigning a value to securities in the event of liquidation. Accordingly, the Board has decided to retain the proposed language in

[10] The text of the provision in NCUA's rule uses the word ''must'' instead of the word ''shall,'' which is used in the FDIC rule, the provisions are otherwise identical. No material difference is intended by the use of the word must instead of the word shall in NCUA's rule.

§§ 709.10(b)(1)(ii)(A) and (B) in the final rule without change.

C. Disclosure

For all securitizations, disclosure serves as an effective tool for increasing the demand for high quality financial assets and thereby establishing incentives for robust financial asset underwriting and origination practices. Consistent with the Proposal, this final rule increases transparency in securitizations by enabling investors to decide whether to invest in a securitization based on full information with respect to the quality of the asset pool and thereby provide additional liquidity only for sustainable origination practices.

The data must enable investors to analyze the credit quality for the specific asset classes that are being securitized. The documents governing securitizations must, at a minimum, require disclosure for all issuances to include the types of information required under current Regulation AB or any successor disclosure requirements with the level of specificity that applies to public issuances, even if the obligations are issued in a private placement or are not otherwise required to be registered.

The documents governing securitizations that qualify under the rule must require disclosure of the structure of the securitization and the credit and payment performance of the obligations, including the relevant capital or tranche structure and any liquidity facilities and credit enhancements. The disclosure must be required to include the priority of payments and any specific subordination features, as well as any waterfall triggers or priority of payment reversal features. The disclosure at issuance must include the representations and warranties made with respect to the financial assets and the remedies for breach of such representations and warranties, including any relevant timeline for cure or repurchase of financial assets, and policies governing delinquencies, servicer advances, loss mitigation and write offs of financial assets. The documents must also require that periodic reports provided to investors include the credit performance of the obligations and financial assets, including periodic and cumulative financial asset performance data, modification data, substitution and removal of financial assets, servicer advances, losses that were allocated to each tranche and remaining balance of financial assets supporting each tranche as well as the percentage coverage for each tranche in relation to the securitization as a whole. Where appropriate for the type of financial assets included in the pool, reports must also include asset level information that may be relevant to investors (*e.g.,* changes in occupancy, loan delinquencies, defaults, etc.). NCUA recognizes that for certain asset classes, such as credit card receivables, the disclosure of asset level information is less informative and, thus, will not be required.

The securitization documents must also require disclosure to investors of the nature and amount of compensation paid to any mortgage or other broker, the servicer(s), rating agency or third-party advisor, and the originator or sponsor, and the extent to which any risk of loss on the underlying financial assets is retained by any of them for such securitization. The documents must require disclosure of changes to this information while obligations are outstanding. This disclosure should enable investors to assess potential conflicts of interests and how the compensation structure affects the quality of the assets securitized or the securitization as a whole.

For RMBS, consistent with the Proposal, this final rule requires the sponsor to disclose loan level data as to the financial assets securing the mortgage loans, such as loan type, loan structure, maturity, interest rate and location of property. Sponsors of securitizations of residential mortgages will be required to affirm compliance in all material respects with applicable statutory and regulatory standards for origination of mortgage loans. None of the disclosure conditions should be construed as requiring the disclosure of personally identifiable information of obligors or information that would violate applicable privacy laws. The rule requires sponsors to disclose a third-party due diligence report on compliance with standards and representations and warranties made about the financial assets.

Finally, this final rule, consistent with the Proposal, specifies that the securitization documents require disclosure by servicers of any ownership interest of the servicer or any affiliate of the servicer in other whole loans secured by the same real property that secures a loan included in the financial asset pool. This provision does not require disclosure of interests held by servicers or their affiliates in the securitization securities. This provision is intended to give investors information to evaluate potential servicer conflicts of interest that might impede the servicer's actions to maximize value for the benefit of investors.

D. Documentation and Recordkeeping

For all securitizations, this final rule, consistent with the Proposal, requires operative agreements to use available standardized documentation for each available asset class. It is not possible to define in advance when use of standardized documentation will be appropriate, but when there is general market use of a form of documentation for a particular asset class, or where a trade group has formulated standardized documentation generally accepted by the industry, such documentation must be used.

Consistent with the Proposal, the rule also requires that securitization documents define the contractual rights and responsibilities of the parties, including but not limited to representations and warranties, ongoing disclosure requirements and any measures to avoid conflicts of interest. The documents are required to provide authority for the parties to fulfill their rights and responsibilities under the securitization contracts.

Consistent with the Proposal, additional conditions apply to RMBS to address a significant issue that has been demonstrated in the mortgage crisis by requiring that servicers have authority to mitigate losses on mortgage loans consistent with maximizing net present value of the mortgages. Therefore, for RMBS, contractual provisions in the servicing agreement must provide servicers with authority to modify loans to address reasonably foreseeable defaults and to take other action to maximize the value and minimize losses on the securitized financial assets. The documents must require servicers to apply industry best practices related to asset management and servicing.

The RMBS documents may not give control of servicing discretion to a particular class of investors. The documents must require that the servicer act for the benefit of all investors rather than for the benefit of any particular class of investors. Consistent with the forgoing, the documents must require the servicer to commence action to mitigate losses no later than ninety days after an asset first becomes delinquent unless all delinquencies on such an asset have been cured. A servicer must be required to maintain sufficient records of its actions to permit appropriate review of its actions.

In January 2013, the Consumer Financial Protection Bureau (''CFPB'') adopted mortgage loan servicing requirements that became effective on

January 10, 2014. One of the requirements, set forth in Subpart C to Regulation X, at 12 CFR 1024.41, generally prohibits a servicer from commencing a foreclosure unless the borrower's mortgage loan obligation is more than 120 days delinquent. This section of Regulation X also provides additional rules that, among other things, require a lender to further delay foreclosure if the borrower submits a loss mitigation application before the lender has commenced the foreclosure process, and requires a lender to delay a foreclosure for which it has commenced the foreclosure process if a borrower has submitted a complete loss mitigation application more than 37 days before a foreclosure sale.[11]

In response to this change, the Board is now making minor amendments in this final rule to clarify that the 90-day loss mitigation requirement does not conflict with the foreclosure commencement delays mandated by the CFPB under Regulation X. In particular, § 709.10(b)(3)(ii)(A) retains the original language proposed, but now includes additional language stating that the loss mitigation action requirement thereunder ''will not be deemed to require that the documents include any provision concerning loss mitigation that requires any action that may conflict with the requirements of Regulation X. . . .''

In addition, NCUA believes that a prolonged period of servicer advances in a market downturn misaligns servicer incentives with those of the RMBS investors. Servicing advances also serve to aggravate liquidity concerns, exposing the market to greater systemic risk. Occasional advances for late payments, however, are beneficial to ensure that investors are paid in a timely manner. To that end, consistent with the Proposal, the servicing agreement for RMBS must not require the primary servicer to advance delinquent payments of principal and interest by borrowers for more than three payment periods unless financing or reimbursement facilities to fund or reimburse the primary servicers are available. However, such facilities shall not be dependent for repayment on foreclosure proceeds.

E. Compensation

Consistent with the Proposal, the compensation requirements of this final rule apply only to RMBS. Due to the demonstrated issues in the compensation incentives in RMBS, the rule seeks to realign compensation to parties involved in the rating and servicing of residential mortgage securitizations.

The securitization documents are required to provide that any fees payable credit rating agencies or similar third-party evaluation companies must be payable in part over the five-year period after the initial issuance of the obligations based on the performance of surveillance services and the performance of the financial assets, with no more than 60% of the total estimated compensation due at closing. Thus, payments to rating agencies must be based on the actual performance of the financial assets, not their ratings.

A second area of concern is aligning incentives for proper servicing of the mortgage loans. Therefore, the documents must require that compensation to servicers must include incentives for servicing, including payment for loan restructuring or other loss mitigation activities, which maximizes the net present value of the financial assets in the RMBS.

F. Origination and Retention Requirements

As discussed above and consistent with the Proposal, this final rule imposes conditions addressing origination and retention requirements for all securitizations to provide further incentives for quality origination practices. Because the regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act have now gone into effect,[12] the Board has amended this final rule to eliminate the references to the retention requirements for securities issued prior to the effective dates of that rulemaking. Accordingly, the final rule now provides that for any securitization, the documents creating the securitization shall require retention of an economic interest in the credit risk of the financial assets in accordance with the regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, including restrictions on sale, pledging and hedging set forth therein.

The Board continues to believe that requiring the sponsor to retain an economic interest in the credit risk relating to each credit tranche or in a representative sample of financial assets will help ensure quality origination practices. A risk retention requirement that did not cover all types of exposure would not be sufficient to create an incentive for quality underwriting at all levels of the securitization. The recent economic crisis made clear that, if quality underwriting is to be assured, it will require true risk retention by sponsors, and that the existence of representations and warranties or regulatory standards for underwriting will not alone be sufficient.

G. Additional Conditions

Consistent with the Proposal, § 709.10(c) of this final rule includes general conditions for securitizations and the transfer of financial assets. These conditions also include requirements that are consistent with good financial institution practices.

The transaction should be an arms-length, bona fide securitization transaction and the documents must limit sales to credit union service organizations in which the sponsor credit union has an interest (other than a wholly-owned credit union service organization consolidated for accounting and capital purposes with the credit union), and insiders of the sponsor. The securitization agreements must be in writing, approved by the board of directors of the credit union or its loan committee (as reflected in the minutes of a meeting of the board of directors or committee), and have been, continuously, from the time of execution, in the official record of the credit union. The securitization must have been entered into in the ordinary course of business, not in contemplation of insolvency and with no intent to hinder, delay or defraud the credit union or its creditors.

The rule applies only to transfers made for adequate consideration. The transfer and/or security interest need to be properly perfected under the Uniform Commercial Code (UCC) or applicable state law. NCUA anticipates that it will be difficult to determine whether a transfer complying with the rule is a sale or a security interest, and therefore expects that a security interest will be properly perfected under the UCC, either directly or as a backup.

The governing documents must require that the sponsor separately identify in its financial asset data bases the financial assets transferred into a securitization and maintain an electronic or paper copy of the closing documents in a readily accessible form, and that the sponsor maintain a current list of all of its outstanding securitizations and issuing entities, and the most recent SEC Form 10–K or other

[11] *See* 12 CFR 1024.41(f) and (g).

[12] 79 FR 77602 (Dec. 24, 2014) (Providing that the effective dates for under the Section 15G Regulations is December 24, 2015 for residential mortgage securitizations and December 24, 2016 for all other securitizations.).

periodic financial report for each securitization and issuing entity. The documents must also provide that if acting as servicer, custodian or paying agent, the sponsor is not permitted to commingle amounts received with respect to the financial assets with its own assets except for the time necessary to clear payments received, and in event for more than two business days. The documents must require the sponsor to make these records available to NCUA promptly upon request. This requirement will facilitate the timely fulfillment of the conservator's or liquidating agent's responsibilities upon appointment and will expedite the conservator's or liquidating agent's analysis of securitization assets. This will also facilitate the conservator's or liquidating agent's analysis of the credit union's assets and determination of which assets have been securitized and are therefore potentially eligible for expedited access by investors.

In addition, the rule requires that the transfer of financial assets and the duties of the sponsor as transferor be evidenced by an agreement separate from the agreement governing the sponsor's duties, if any, as servicer, custodian, paying agent, credit support provider or in any capacity other than transferor.

H. The Safe Harbor

Consistent with the Proposal, § 709.10(d)(1) of the rule continues the safe harbor provision that was provided by the 2000 Rule with respect to participations so long as the participation satisfies the conditions for sale accounting treatment set forth by generally accepted accounting principles. In addition, last-in first-out participations are specifically included in the safe harbor, provided that they satisfy requirements for sale accounting treatment other than the pari-passu, proportionate interest requirement that is not satisfied solely as a result of the last-in first-out structure.

Consistent with the Proposal, § 709.10(d)(2) of the Rule addresses transfers of financial assets made in connection with a securitization for which transfers of financial assets are made after the effective date of this rule or securitizations from a master trust or revolving trust established after the date of adoption of this rule, that (in each case) satisfy the conditions for sale accounting treatment under GAAP in effect for reporting periods after November 15, 2009. For such securitizations, NCUA as conservator or liquidating agent will not, in the exercise of its statutory authority to disaffirm or repudiate contracts, reclaim, recover, or recharacterize as property of the institution or the liquidation estate any such transferred financial assets, provided that such securitizations comply with the conditions set forth in paragraphs (b) and (c) of the rule.

Consistent with the Proposal, § 709.10(d)(3) of the Rule addresses transfers of financial assets in connection with a securitization for which transfers of financial assets were made after the effective date of this rule or securitizations from a master trust or revolving trust established after the date of adoption of the rule, that (in each case) satisfy the conditions set forth in paragraphs (b) and (c), but where the transfer does not satisfy the conditions for sale accounting treatment under GAAP in effect for reporting periods after November 15, 2009.

Consistent with the Proposal, § 709.10(d)(3)(i) provides that if the conservator or liquidating agent is in monetary default due to its failure to pay or apply collections from the financial assets received by it in accordance with the securitization documents, and remains in monetary default for ten business days after actual delivery of a written notice to the conservator or liquidating agent requesting exercise of contractual rights because of such default, the conservator or liquidating agent consents to the exercise of such contractual rights, including any rights to obtain possession of the financial assets or the exercise of self-help remedies as a secured creditor, provided that no involvement of the conservator or liquidating agent is required, other than consents, waivers or the execution of transfer documents reasonably requested in the ordinary course of business in order facilitate the exercise of such contractual rights. This paragraph also provides that the consent to the exercise of such contractual rights shall serve as full satisfaction for all amounts due.

Consistent with the Proposal, § 709.10(d)(3)(ii) provides that, if the conservator or liquidating agent gives a written notice of repudiation of the securitization agreement pursuant to which assets were transferred and does not pay the damages due by reason of such repudiation within ten business days following the effective date of the notice, the conservator or liquidating agent consents to the exercise of any contractual rights, including any rights to obtain possession of the financial assets or the exercise of self-help remedies as a secured creditor, provided that no involvement of the conservator or liquidating agent is required other than consents, waivers or the execution of transfer documents reasonably requested in the ordinary course of business in order facilitate the exercise of such contractual rights. Paragraph 3(d)(ii) also provides that the damages due for these purposes shall be an amount equal to the par value of the obligations outstanding on the date of liquidation less any payments of principal received by the investors through the date of repudiation, plus unpaid, accrued interest through the date of repudiation to the extent actually received through payments on the financial assets received through the date of repudiation, and that upon receipt of such payment all liens on the financial assets created pursuant to the securitization documents shall be released.

In computing amounts payable as repudiation damages, consistent with the FCU Act, the conservator or liquidating agent will not give effect to any provisions of the securitization documents increasing the amount payable based on the appointment of as the conservator or liquidating agent.[13] The rule clarifies that repudiation damages will be equal to the par value of the obligations as of the date of liquidation, less payments of principal received by the investors to the date of repudiation, plus unpaid, accrued interest through the date of repudiation to the extent actually received through payments on the financial assets received through the date of repudiation. The rule also provides that the conservator or liquidating agent consents to the exercise of remedies by investors, including self-help remedies as secured creditors, in the event that NCUA repudiates a securitization transfer agreement and does not pay damages in such amount within ten business days following the effective date of notice of repudiation. Thus, if NCUA repudiates and the investors are not paid the par value of the securitization obligations, plus unpaid, accrued interest through the date of repudiation to the extent actually received through payments on the financial assets received through the date of repudiation, they will be permitted to obtain the asset pool. Accordingly, exercise by the conservator or the liquidating agent of its repudiation rights will not expose investors to market value risks relating to the asset pool.

[13] 12 U.S.C. 1787(c)(13).

I. Consent to Certain Payments and Servicing

Consistent with the Proposal, § 709.10(e) provides that prior to repudiation or, in the case of monetary default, prior to the effectiveness of the consent referred to in § 709.10(d)(3)(i), the conservator or liquidating agent consents to the making of, or if acting as servicer agrees to make, required payments to the investors during the stay period imposed by 12 U.S.C. 1787(c)(13)(C). The rule also provides that the conservator or liquidating agent consents to any servicing activity required in furtherance of the securitization (subject to its rights to repudiate the servicing agreements), in connection with securitizations that meet the conditions set forth in paragraphs (b) and (c) of § 709.10 of the rule.

J. Miscellaneous

Consistent with the Proposal, § 709.10(f) requires that any party requesting consent pursuant to paragraph (d)(3), provide notice to the conservator or liquidating agent, together with a statement of the basis upon which the request is made, together with copies of all documentation supporting the request. This includes a copy of the applicable agreements (such as the transfer agreement and the security agreement) and of any applicable notices under the agreements.

Consistent with the Proposal, § 709.10(g) provides that the conservator or liquidating agent will not seek to avoid an otherwise legally enforceable agreement that is executed by a FICU in connection with a securitization solely because the agreement does not meet the ''contemporaneous'' requirement of 12 U.S.C. 1787(b)(9) and 1788(a)(3).

Consistent with the Proposal, § 709.10(h) of the rule provides that the consents set forth in the rule will not act to waive or relinquish any rights granted to NCUA, the conservator, or the liquidating agent, in any capacity, pursuant to any other applicable law or any agreement or contract except as specifically set forth in the rule, and nothing contained in the section will alter the claims priority of the securitized obligations.

Consistent with the Proposal, § 709.10(i) provides that except as specifically set forth in the rule, the rule does not authorize, and shall not be construed as authorizing the attachment of any involuntary lien upon the property of the conservator or liquidating agent. The rule should not be construed as waiving, limiting or otherwise affecting the rights or powers of NCUA, the conservator, or the liquidating agent to take any action or to exercise any power not specifically mentioned, including but not limited to any rights, powers or remedies of the conservator or the liquidating agent regarding transfers taken in contemplation of the FICU's insolvency or with the intent to hinder, delay or defraud the FICU, or the creditors of such FICU, or that is a fraudulent transfer under applicable law.

The right to consent under 12 U.S.C. 1787(c)(13)(C) may not be assigned or transferred to any purchaser of property from a conservator or liquidating agent, other than to a conservator or bridge credit union. The rule can be repealed by NCUA upon 30 days' notice provided in the **Federal Register**, but any repeal will not apply to any issuance that complied with the rule before such repeal.

III. Regulatory Procedures

1. Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis of any significant economic impact any proposed regulation may have on a substantial number of small entities (primarily those under $100 million in assets).[14] The final rule will apply only to the largest credit unions, as they are the only ones with the infrastructure and resources to securitize assets. Accordingly, the Board certifies it will not have an economic impact on any small credit unions.

2. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or increases an existing burden.[15] For purposes of the PRA, a paperwork burden may take the form of a reporting or recordkeeping requirement, both referred to as information collections. The changes to part 709 impose new information collection requirements.

Estimated PRA Burden: The information collection requirements are related to federal security filings. As discussed above, because this final rule is based on 12 CFR 360.6, the NCUA has also based its information collection requirements on the information collection estimates provided under that regulation. According, NCUA's burden estimates for the applications are as follows:

1. 10K Annual Report

Non Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 1 time per year.
Average Time per Response: 27 hours.
Estimated Annual Burden: 54 hours.
Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 1 time per year.
Average Time per Response: 4.5 hours.
Estimated Annual Burden: 9 hours.

2. 8K Annual Report

Non Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 2 time per year.
Average Time per Response: 27 hours.
Estimated Annual Burden: 108 hours.
Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 2 time per year.
Average Time per Response: 4.5 hours.
Estimated Annual Burden: 18 hours.

3. 10D Annual Report

Non Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 5 time per year.
Average Time per Response: 27 hours.
Estimated Annual Burden: 270 hours.
Reg AB Compliant:
Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 5 time per year.
Average Time per Response: 4.5 hours.
Estimated Annual Burden: 45 hours.

4. 12b–25 Notification

Estimated Number of Respondents: 2.
Affected Public: NCUA-insured credit unions.
Frequency of Response: 2 time per year.
Average Time per Response: 2.5 hours.
Estimated Annual Burden: 10 hours.

3. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to

[14] 5 U.S.C. 603(a); 12 U.S.C. 1787(c)(1).
[15] 44 U.S.C. 3507(d); 5 CFR part 1320.

consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This final rule does 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. NCUA has therefore determined that this final does not constitute a policy that has federalism implications for purposes of the executive order.

4. Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

5. Small Business Regulatory Enforcement Act Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedure Act.[16] NCUA does not believe this final rule is a ''major rule'' within the meaning of the relevant sections of SBREFA. As required by SBREFA, NCUA has filed the appropriate reports so that this final rule may be reviewed.

List of Subjects in 12 CFR Part 709

Credit unions, Liquidations.

By the National Credit Union Administration Board, on June 23, 2017.

Gerard Poliquin,

Secretary of the Board.

For the reasons discussed above, the National Credit Union Administration amends 12 CFR part 709 as follows:

PART 709—INVOLUNTARY LIQUIDATION OF FEDERAL CREDIT UNIONS AND ADJUDICATION OF CREDITOR CLAIMS INVOLVING FEDERALLY INSURED CREDIT UNIONS IN LIQUIDATION

■ 1. The authority citation for part 709 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766, 1767, 1786(h), 1787, 1789, 1789a.

■ 2. Revise § 709.10 to read as follows:

[16] 5 U.S.C. 551.

§ 709.10 Treatment of financial assets transferred in connection with a securitization or participation.

(a) *Definitions.*

Financial asset means cash or a contract or instrument that conveys to one entity a contractual right to receive cash or another financial instrument from another entity.

Investor means a person or entity that owns an obligation issued by an issuing entity.

Issuing entity means an entity that owns a financial asset or financial assets transferred by the sponsor and issues obligations supported by such asset or assets. Issuing entities may include, but are not limited to, corporations, partnerships, trusts, and limited liability companies and are commonly referred to as special purpose vehicles or special purpose entities. To the extent a securitization is structured as a multi-step transfer, the term issuing entity would include both the issuer of the obligations and any intermediate entities that may be a transferee. Notwithstanding the foregoing, a Specified GSE or an entity established or guaranteed by a Specified GSE does not constitute an issuing entity.

Monetary default means a default in the payment of principal or interest when due following the expiration of any cure period.

Obligation means a debt or equity (or mixed) beneficial interest or security that is primarily serviced by the cash flows of one or more financial assets or financial asset pools, either fixed or revolving, that by their terms convert into cash within a finite time period, or upon the disposition of the underlying financial assets, and by any rights or other assets designed to assure the servicing or timely distributions of proceeds to the security holders issued by an issuing entity. The term may include beneficial interests in a grantor trust, common law trust or similar issuing entity to the extent that such interests satisfy the criteria set forth in the preceding sentence, but does not include LLC interests, partnership interests, common or preferred equity, or similar instruments evidencing ownership of the issuing entity.

Participation means the transfer or assignment of an undivided interest in all or part of a financial asset, that has all of the characteristics of a ''participating interest,'' from a seller, known as the ''lead,'' to a buyer, known as the ''participant,'' without recourse to the lead, pursuant to an agreement between the lead and the participant. ''Without recourse'' means that the participation is not subject to any agreement that requires the lead to repurchase the participant's interest or to otherwise compensate the participant upon the borrower's default on the underlying obligation.

Securitization means the issuance by an issuing entity of obligations for which the investors are relying on the cash flow or market value characteristics and the credit quality of transferred financial assets (together with any external credit support permitted by this section) to repay the obligations.

Servicer means any entity responsible for the management or collection of some or all of the financial assets on behalf of the issuing entity or making allocations or distributions to holders of the obligations, including reporting on the overall cash flow and credit characteristics of the financial assets supporting the securitization to enable the issuing entity to make payments to investors on the obligations. The term ''servicer'' does not include a trustee for the issuing entity or the holders of obligations that makes allocations or distributions to holders of the obligations if the trustee receives such allocations or distributions from a servicer and the trustee does not otherwise perform the functions of a servicer.

Specified GSE means each of the following:

(1) The Federal National Mortgage Association and any affiliate thereof;

(2) Federal Home Loan Mortgage Corporation and any affiliate thereof;

(3) The Government National Mortgage Association; and

(4) Any Federal or State sponsored mortgage finance agency.

Sponsor means a person or entity that organizes and initiates a securitization by transferring financial assets, either directly or indirectly, including through an affiliate, to an issuing entity, whether or not such person owns an interest in the issuing entity or owns any of the obligations issued by the issuing entity.

Transfer means:

(1) The conveyance of a financial asset or financial assets to an issuing entity; or

(2) The creation of a security interest in such asset or assets for the benefit of the issuing entity.

(b) *Coverage.* This section applies to securitizations that meet the following criteria:

(1) *Capital structure and financial assets.* The documents creating the securitization must define the payment structure and capital structure of the transaction.

(i) *Requirements applicable to all securitizations.* (A) The securitization may not consist of re-securitizations of

obligations or collateralized debt obligations unless the documents creating the securitization require that disclosures required in paragraph (b)(2) of this section are made available to investors for the underlying assets supporting the securitization at initiation and while obligations are outstanding; and

(B) The documents creating the securitization must require that payment of principal and interest on the securitization obligation will be primarily based on the performance of financial assets that are transferred to the issuing entity and, except for interest rate or currency mismatches between the financial assets and the obligations, will not be contingent on market or credit events that are independent of such financial assets. The securitization may not be an unfunded securitization or a synthetic transaction.

(ii) *Requirements applicable only to securitizations in which the financial assets include any residential mortgage loans.* (A) The capital structure of the securitization must be limited to no more than six credit tranches and cannot include ''sub-tranches,'' grantor trusts or other structures. Notwithstanding the foregoing, the most senior credit tranche may include time-based sequential pay or planned amortization and companion sub-tranches; and

(B) The credit quality of the obligations cannot be enhanced at the issuing entity or pool level through external credit support or guarantees. However, the credit quality of the obligations may be enhanced by credit support or guarantees provided by Specified GSEs and the temporary payment of principal and/or interest may be supported by liquidity facilities, including facilities designed to permit the temporary payment of interest following appointment of the NCUA Board as conservator or liquidating agent. Individual financial assets transferred into a securitization may be guaranteed, insured, or otherwise benefit from credit support at the loan level through mortgage and similar insurance or guarantees, including by private companies, agencies or other governmental entities, or government-sponsored enterprises, and/or through co-signers or other guarantees.

(2) *Disclosures.* The documents must require that the sponsor, issuing entity, and/or servicer, as appropriate, will make available to investors, information describing the financial assets, obligations, capital structure, compensation of relevant parties, and relevant historical performance data set forth in this paragraph (b)(2).

(i) *Requirements applicable to all securitizations.* (A) The documents must require that, on or prior to issuance of obligations and at the time of delivery of any periodic distribution report and, in any event, at least once per calendar quarter, while obligations are outstanding, information about the obligations and the securitized financial assets will be disclosed to all potential investors at the financial asset or pool level and security level, as appropriate for the financial assets, to enable evaluation and analysis of the credit risk and performance of the obligations and financial assets. The documents must require that such information and its disclosure, at a minimum, complies with the requirements of Securities and Exchange Commission Regulation AB, or any successor disclosure requirements for public issuances, even if the obligations are issued in a private placement or are not otherwise required to be registered. Information that is unknown or not available to the sponsor or the issuer after reasonable investigation may be omitted if the issuer includes a statement in the offering documents disclosing that the specific information is otherwise unavailable.

(B) The documents must require that, on or prior to issuance of obligations, the structure of the securitization and the credit and payment performance of the obligations will be disclosed, including the capital or tranche structure, the priority of payments, and specific subordination features; representations and warranties made with respect to the financial assets, the remedies for, and the time permitted for cure of any breach of representations and warranties, including the repurchase of financial assets, if applicable; liquidity facilities and any credit enhancements permitted by this rule, any waterfall triggers, or priority of payment reversal features; and policies governing delinquencies, servicer advances, loss mitigation, and write-offs of financial assets.

(C) The documents must require that while obligations are outstanding, the issuing entity will provide to investors information with respect to the credit performance of the obligations and the financial assets, including periodic and cumulative financial asset performance data, delinquency and modification data for the financial assets, substitutions and removal of financial assets, servicer advances, as well as losses that were allocated to such tranche and remaining balance of financial assets supporting such tranche, if applicable, and the percentage of each tranche in relation to the securitization as a whole.

(D) In connection with the issuance of obligations, the documents must disclose the nature and amount of compensation paid to the originator, sponsor, rating agency or third-party advisor, any mortgage or other broker, and the servicer(s), and the extent to which any risk of loss on the underlying assets is retained by any of them for such securitization be disclosed. The securitization documents must require the issuer to provide to investors while obligations are outstanding any changes to such information and the amount and nature of payments of any deferred compensation or similar arrangements to any of the parties.

(ii) *Requirements applicable only to securitizations in which the financial assets include any residential mortgage loans.* (A) Prior to issuance of obligations, sponsors must disclose loan level information about the financial assets including, but not limited to, loan type, loan structure (for example, fixed or adjustable, resets, interest rate caps, balloon payments, etc.), maturity, interest rate and/or Annual Percentage Rate, and location of the property.

(B) Prior to issuance of obligations, sponsors must affirm compliance in all material respects with applicable statutory and regulatory standards for the underwriting and origination of residential mortgage loans. Sponsors must disclose a third-party due diligence report on compliance with such standards and the representations and warranties made with respect to the financial assets.

(C) The documents must require that prior to issuance of obligations and while obligations are outstanding, servicers will disclose any ownership interest by the servicer or an affiliate of the servicer in other whole loans secured by the same real property that secures a loan included in the financial asset pool. The ownership of an obligation, as defined in this regulation, does not constitute an ownership interest requiring disclosure.

(3) *Documentation and recordkeeping.* The documents creating the securitization must specify the respective contractual rights and responsibilities of all parties and include the requirements described in paragraph (b)(3) of this section and use as appropriate any available standardized documentation for each different asset class.

(i) *Requirements applicable to all securitizations.* The documents must define the contractual rights and responsibilities of the parties, including but not limited to representations and

warranties and ongoing disclosure requirements, and any measures to avoid conflicts of interest; and provide authority for the parties, including but not limited to the originator, sponsor, servicer, and investors, to fulfill their respective duties and exercise their rights under the contracts and clearly distinguish between any multiple roles performed by any party.

(ii) *Requirements applicable only to securitizations in which the financial assets include any residential mortgage loans.* (A) Servicing and other agreements must provide servicers with authority, subject to contractual oversight by any master servicer or oversight advisor, if any, to mitigate losses on financial assets consistent with maximizing the net present value of the financial asset. Servicers shall have the authority to modify assets to address reasonably foreseeable default, and to take other action to maximize the value and minimize losses on the securitized financial assets. The documents shall require that the servicers apply industry best practices for asset management and servicing. The documents shall require the servicer to act for the benefit of all investors, and not for the benefit of any particular class of investors, that the servicer maintain records of its actions to permit full review by the trustee or other representative of the investors and that the servicer must commence action to mitigate losses no later than ninety (90) days after an asset first becomes delinquent unless all delinquencies have been cured, *provided* that this requirement will not be deemed to require that the documents include any provision concerning loss mitigation that requires any action that may conflict with the requirements of Regulation X (12 CFR part 1024), as Regulation X may be amended or modified from time to time.

(B) The servicing agreement may not require a primary servicer to advance delinquent payments of principal and interest for more than three payment periods, unless financing or reimbursement facilities are available, which may include, but are not limited to, the obligations of the master servicer or issuing entity to fund or reimburse the primary servicer, or alternative reimbursement facilities. Such ''financing or reimbursement facilities'' under this paragraph may not be dependent for repayment on foreclosure proceeds.

(4) *Compensation.* The following requirements apply only to securitizations in which the financial assets include any residential mortgage loans. Compensation to parties involved in the securitization of such financial assets must be structured to provide incentives for sustainable credit and the long-term performance of the financial assets and securitization as follows:

(i) The documents must require that any fees or other compensation for services payable to credit rating agencies or similar third-party evaluation companies are payable, in part, over the five-year period after the first issuance of the obligations based on the performance of surveillance services and the performance of the financial assets, with no more than sixty percent of the total estimated compensation due at closing; and

(ii) The documents must provide that compensation to servicers will include incentives for servicing, including payment for loan restructuring or other loss mitigation activities, which maximizes the net present value of the financial assets. Such incentives may include payments for specific services, and actual expenses, to maximize the net present value or a structure of incentive fees to maximize the net present value, or any combination of the foregoing that provides such incentives.

(5) *Origination and retention requirements*—(i) *Requirements applicable to all securitizations.* For any securitization, the documents creating the securitization shall require retention of an economic interest in the credit risk of the financial assets in accordance with the regulations required under Section 15G of the Securities Exchange Act, 15 U.S.C. 78a *et seq.,* added by Section 941(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, including restrictions on sale, pledging and hedging set forth therein.

(ii) *Requirements applicable only to securitizations in which the financial assets include any residential mortgage loans.* (A) The documents must require the establishment of a reserve fund equal to at least five (5) percent of the cash proceeds of the securitization payable to the sponsor to cover the repurchase of any financial assets required for breach of representations and warranties. The balance of such fund, if any, must be released to the sponsor one year after the date of issuance.

(B) The documents must include a representation that the assets were originated in all material respects in compliance with statutory, regulatory, and originator underwriting standards in effect at the time of origination. The documents must include a representation that the mortgages included in the securitization were underwritten at the fully indexed rate, based upon the borrowers' ability to repay the mortgage according to its terms, and rely on documented income and comply with all existing all laws, rules, regulations, and guidance governing the underwriting of residential mortgages by federally insured credit unions.

(c) *Other requirements.* (1) The transaction should be an arms-length, bona fide securitization transaction. The documents must require that the obligations issued in a securitization shall not be predominantly sold to a credit union service organization in which the sponsor credit union has an interest (other than a wholly-owned credit union service organization consolidated for accounting and capital purposes with the credit union) or insider of the sponsor;

(2) The securitization agreements are in writing, approved by the board of directors of the credit union or its loan committee (as reflected in the minutes of a meeting of the board of directors or committee), and have been, continuously, from the time of execution in the official record of the credit union;

(3) The securitization was entered into in the ordinary course of business, not in contemplation of insolvency and with no intent to hinder, delay, or defraud the credit union or its creditors;

(4) The transfer was made for adequate consideration;

(5) The transfer and/or security interest was properly perfected under the UCC or applicable state law;

(6) The transfer and duties of the sponsor as transferor must be evidenced in a separate agreement from its duties, if any, as servicer, custodian, paying agent, credit support provider, or in any capacity other than the transferor; and

(7) The documents must require that the sponsor separately identify in its financial asset data bases the financial assets transferred into any securitization and maintain (i) an electronic or paper copy of the closing documents for each securitization in a readily accessible form, (ii) a current list of all of its outstanding securitizations and the respective issuing entities, and (iii) the most recent Securities and Exchange Commission Form 10-K, if applicable, or other periodic financial report for each securitization and issuing entity. The documents must provide that to the extent serving as servicer, custodian, or paying agent for the securitization, the sponsor may not comingle amounts received with respect to the financial assets with its own assets except for the time, not to exceed two business days, necessary to clear any payments received. The documents must require that the sponsor will make these records

readily available for review by NCUA promptly upon written request.

(d) *Safe harbor*—(1) *Participations.* With respect to transfers of financial assets made in connection with participations, the NCUA Board as conservator or liquidating agent will not, in the exercise of its statutory authority to disaffirm or repudiate contracts, reclaim, recover, or recharacterize as property of the credit union or the liquidation estate any such transferred financial assets, provided that such transfer satisfies the conditions for sale accounting treatment under generally accepted accounting principles, except for the ''legal isolation'' condition that is addressed by this section. The foregoing sentence applies to a last-in, first-out participation, provided that the transfer of a portion of the financial asset satisfies the conditions for sale accounting treatment under generally accepted accounting principles that would have applied to such portion if it had met the definition of a ''participating interest,'' except for the ''legal isolation'' condition that is addressed by this section.

(2) *For securitizations meeting sale accounting requirements.* With respect to any securitization for which transfers of financial assets were made after adoption of this rule, or from a master trust or revolving trust established after adoption of this rule, and which complies with the requirements applicable to that securitization as set forth in paragraphs (b) and (c) of this section, the NCUA Board as conservator or liquidating agent will not, in the exercise of its statutory authority to disaffirm or repudiate contracts, reclaim, recover, or recharacterize as property of the credit union or the liquidation estate such transferred financial assets, provided that such transfer satisfies the conditions for sale accounting treatment under generally accepted accounting principles in effect for reporting periods after November 15, 2009, except for the ''legal isolation'' condition that is addressed by this paragraph (d)(2).

(3) *For securitizations not meeting sale accounting requirements.* With respect to any securitization for which transfers of financial assets were made after adoption of this rule, or from a master trust or revolving trust established after adoption of this rule, and which complies with the requirements applicable to that securitization as set forth in paragraphs (b) and (c) of this section, but where the transfer does not satisfy the conditions for sale accounting treatment set forth by generally accepted accounting principles in effect for reporting periods after November 15, 2009, the following conditions apply:

(i) *Monetary default.* If, at any time after appointment, the NCUA Board as conservator or liquidating agent is in a monetary default under a securitization due to its failure to pay or apply collections from the financial assets received by it in accordance with the securitization documents, whether as servicer or otherwise, and remains in monetary default for ten business days after actual delivery of a written notice to the NCUA Board as conservator or liquidating agent pursuant to paragraph (f) of this section requesting the exercise of contractual rights because of such monetary default, the NCUA Board as conservator or liquidating agent hereby consents pursuant to 12 U.S.C. 1787(c)(13)(C) to the exercise of any contractual rights in accordance with the documents governing such securitization, including but not limited to taking possession of the financial assets and exercising self-help remedies as a secured creditor under the transfer agreements, provided no involvement of the conservator or liquidating agent is required other than such consents, waivers, or execution of transfer documents as may be reasonably requested in the ordinary course of business in order to facilitate the exercise of such contractual rights. Such consent does not waive or otherwise deprive the NCUA Board as conservator or liquidating agent or its assignees of any seller's interest or other obligation or interest issued by the issuing entity and held by the conservator or liquidating agent or its assignees, but shall serve as full satisfaction of the obligations of the insured credit union in conservatorship or liquidation and the NCUA Board as conservator or liquidating agent for all amounts due.

(ii) *Repudiation.* If the NCUA Board as conservator or liquidating agent provides a written notice of repudiation of the securitization agreement pursuant to which the financial assets were transferred, and does not pay damages, defined in this paragraph, within ten business days following the effective date of the notice, the NCUA Board as conservator or liquidating agent hereby consents pursuant to 12 U.S.C. 1787(c)(13)(C) to the exercise of any contractual rights in accordance with the documents governing such securitization, including but not limited to taking possession of the financial assets and exercising self-help remedies as a secured creditor under the transfer agreements, provided no involvement of the conservator or liquidating agent is required other than such consents, waivers, or execution of transfer documents as may be reasonably requested in the ordinary course of business in order to facilitate the exercise of such contractual rights. For purposes of this paragraph, the damages due will be in an amount equal to the par value of the obligations outstanding on the date of appointment of the conservator or liquidating agent, less any payments of principal received by the investors through the date of repudiation, plus unpaid, accrued interest through the date of repudiation in accordance with the contract documents to the extent actually received through payments on the financial assets received through the date of repudiation. Upon payment of such repudiation damages, all liens or claims on the financial assets created pursuant to the securitization documents shall be released. Such consent does not waive or otherwise deprive the NCUA Board as conservator or liquidating agent or its assignees of any seller's interest or other obligation or interest issued by the issuing entity and held by the conservator or liquidating agent or its assignees, but serves as full satisfaction of the obligations of the insured credit union in conservatorship or liquidation and the NCUA Board as conservator or liquidating agent for all amounts due.

(iii) *Effect of repudiation.* If the NCUA Board as conservator or liquidating agent repudiates or disaffirms a securitization agreement, it will not assert that any interest payments made to investors in accordance with the securitization documents before any such repudiation or disaffirmance remain the property of the conservatorship or liquidation.

(e) *Consent to certain actions.* Prior to repudiation or, in the case of a monetary default referred to in paragraph (d)(3)(i) of this section, prior to the effectiveness of the consent referred to therein, the NCUA Board as conservator or liquidating agent consents pursuant to 12 U.S.C. 1787(c)(13)(C) to the making of, or if serving as servicer, does make, the payments to the investors to the extent actually received through payments on the financial assets (but in the case of repudiation, only to the extent supported by payments on the financial assets received through the date of the giving of notice of repudiation) in accordance with the securitization documents, and, subject to the conservator's or liquidating agent's rights to repudiate such agreements, consents to any servicing activity required in furtherance of the securitization or, if acting as servicer, the conservator or liquidating agent

performs such servicing activities in accordance with the terms of the applicable servicing agreements, with respect to the financial assets included in securitizations that meet the requirements applicable to that securitization as set forth in paragraphs (b) and (c) of this section.

(f) *Notice for consent.* Any party requesting the NCUA Board's consent as conservator or liquidating agent under 12 U.S.C. 1787(c)(13)(C) pursuant to paragraph (d)(3)(i) of this section must provide notice to the President, NCUA Asset Management & Assistance Center, 4807 Spicewood Springs Road, Suite 5100, Austin TX 78759–8490, and a statement of the basis upon which such request is made, and copies of all documentation supporting such request, including without limitation a copy of the applicable agreements and of any applicable notices under the contract.

(g) *Contemporaneous requirement.* The NCUA Board as conservator or liquidating agent will not seek to avoid an otherwise legally enforceable agreement that is executed by an insured credit union in connection with a securitization or in the form of a participation solely because the agreement does not meet the ''contemporaneous'' requirement of 12 U.S.C. 1787(b)(9) and 1788(a)(3).

(h) *Limitations.* The consents set forth in this section do not act to waive or relinquish any rights granted to NCUA in any capacity, including the NCUA Board as conservator or liquidating agent, pursuant to any other applicable law or any agreement or contract except as specifically set forth herein. Nothing contained in this section alters the claims priority of the securitized obligations.

(i) *No waiver.* This section does not authorize the attachment of any involuntary lien upon the property of the NCUA Board as conservator or liquidating agent. Nor does this section waive, limit, or otherwise affect the rights or powers of NCUA in any capacity, including the NCUA Board as conservator or liquidating agent, to take any action or to exercise any power not specifically mentioned, including but not limited to any rights, powers or remedies of the NCUA Board as conservator or liquidating agent regarding transfers or other conveyances taken in contemplation of the credit union's insolvency or with the intent to hinder, delay or defraud the credit union or the creditors of such credit union, or that is a fraudulent transfer under applicable law.

(j) *No assignment.* The right to consent under 12 U.S.C. 1787(c)(13)(C) may not be assigned or transferred to any purchaser of property from the NCUA Board as conservator or liquidating agent, other than to a conservator or bridge credit union.

(k) *Repeal.* This section may be repealed by NCUA upon 30 days' notice provided in the **Federal Register**, but any repeal does not apply to any issuance made in accordance with this section before such repeal.

[FR Doc. 2017–13636 Filed 6–29–17; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 747

RIN 3133–AE67

Civil Monetary Penalty Inflation Adjustment

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: On January 23, 2017, the NCUA Board (Board) published an interim final rule amending its regulations to adjust the maximum amount of each civil monetary penalty (CMP) within its jurisdiction to account for inflation. This action, including the amount of the adjustments, is required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. This rule finalizes those amendments.

DATES: Effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Ian Marenna, Senior Trial Attorney, at 1775 Duke Street, Alexandria, VA 22314, or telephone: (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background

The Debt Collection Improvement Act of 1996 [1] (DCIA) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 [2] (FCPIA Act) to require every federal agency to enact regulations that adjust each CMP provided by law under its jurisdiction by the rate of inflation at least once every four years. In November 2015, Congress further amended the CMP inflation requirements in the Bipartisan Budget Act of 2015,[3] which contains the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 amendments).[4] This legislation provides for an initial ''catch-up'' adjustment of CMPs in 2016, followed by annual inflation adjustments starting in 2017.

On January 23, 2017, in compliance with the 2015 amendments, the Board published the annual inflation adjustments for 2017 in an interim final rule with a request for comments in the **Federal Register**.[5] In calculating the adjustments, the Board reviewed and applied government-wide guidance issued by the Office of Management and Budget (OMB).[6] In accordance with the procedures and calculations prescribed by the 2015 amendments and OMB's guidance, the Board adjusted the maximum level of each of the CMPs that NCUA has authority to assess. NCUA is not, however, required to assess at the new maximum levels and retains discretion to assess at lower levels, as it has done historically.[7]

The interim final rule became effective on January 23, 2017. The Board received no comments on the rule. Accordingly, this final rule confirms the adjustments made in the interim final rule without change.

II. Regulatory Procedures

Section III of the Supplementary Information in the January 2017 interim final rule sets forth the Board's analyses under the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act of 1995, the Small Business Regulatory Enforcement Fairness Act (SBREFA), Executive Order 13132, and the Treasury and General Government Appropriations Act.[8] Because the final rule confirms the interim final rule and does not alter the substance of the analyses and determinations accompanying the interim final rule, the Board continues to rely on those analyses and determinations for purposes of this rulemaking. The Board notes that OMB determined that the interim final rule is not a ''major rule'' within the meaning of SBREFA.

[1] Public Law 104–134, section 31001(s), 110 Stat. 1321–373 (Apr. 26, 1996). The law is codified at 28 U.S.C. 2461 note.

[2] Public Law 101–410, 104 Stat. 890 (Oct. 5, 1990), also codified at 28 U.S.C. 2461 note.

[3] Public Law 114–74, 129 Stat. 584 (Nov. 2, 2015).

[4] 129 Stat. 599.

[5] 82 FR 7637 (Jan. 23, 2017).

[6] Office of Management and Budget, Implementation of the 2017 Annual Adjustment Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, M–17–11 (Dec. 16, 2016).

[7] 82 FR 7637, 7639 (Jan. 23, 2017).

[8] *See* 82 FR 7640.

By the National Credit Union Administration Board on June 23, 2017.

Gerard Poliquin,

Secretary of the Board.

■ For the reasons stated above, the interim final rule amending 12 CFR part 747, published at 82 FR 7637 (Jan. 23, 2017) is adopted as a final rule without change.

[FR Doc. 2017–13643 Filed 6–29–17; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 792

RIN 3133–AD44

Revisions to the Freedom of Information Act Regulation

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (Board) is finalizing its interim final rule amending its Freedom of Information Act (FOIA) regulation. The FOIA Improvement Act of 2016 amended the FOIA and required agencies to review their FOIA regulations and issue certain amendments by December 27, 2016. The amendments included revised procedures for disclosing records under the FOIA, assessing fees, and notifying requestors of options for resolving disputes through the NCUA FOIA Public Liaison and the Office of Government Information Services (OGIS) within the National Archives and Records Administration. The interim final rule became effective on December 22, 2016. This rulemaking finalizes the interim rule with minor edits for consistency and clarification.

DATES: Effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Regina Metz, Senior Staff Attorney, or Linda Dent, Associate General Counsel, Administrative Law Section, Office of General Counsel, at 1775 Duke Street, Alexandria, Virginia 22314–3428, or telephone: (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background

On December 22, 2016, NCUA published an interim final rule [1] to revise its FOIA regulation at part 792, subpart A of the agency's regulations [2] in accordance with new requirements under the FOIA Improvement Act of 2016.[3] The interim final rule became effective on December 22, 2016. The NCUA accepted public comments, however, until January 23, 2017.

The interim final rule revised procedures for the disclosure of records, including procedures for engaging in dispute resolution through the FOIA Public Liaison and the OGIS. The revisions were necessary to comply with amendments to the FOIA Improvement Act of 2016. NCUA is issuing this rulemaking to finalize the interim rule with minor wording changes for consistency and clarification.

II. Summary of Public Comments and Final Rule

NCUA received two comments on the interim final rule. One was from a trade organization and one was from an institute. One comment was fully supportive of the Act, noting that the interim rule met all the technical statutory requirements. The comment, however, also urged the NCUA to exceed the requirements and continue to adopt a presumption of openness. NCUA's longstanding FOIA practices include a presumption of openness which will continue under the final rule.

In addition, the commenter believes the NCUA should post every FOIA response to its Web site. The FOIA and the interim final rule, in section 792.03(c), already provide that NCUA must post on its Web site records released in response to a FOIA request that are either: Likely to be the subject of subsequent requests because of the nature of their subject matter; or records that have been requested three or more times. NCUA generally exceeds these requirements, posting on its FOIA page records requested more than once and considering each record requested for possible routine Web site posting. As every record requested, however, is not of interest to the general public, NCUA is adopting this section in the final rule without change.

The other commenter requested that NCUA revise its definition of ''representative of the news media'' in § 792.20 to be consistent with the FOIA at 5 U.S.C. 552(a)(4)(A)(ii) and also to consider additional technical matters. As a change to this definition and the other issue raised were not included in the interim final rule, NCUA will address this in an upcoming technical amendment rule. The final rule does contain minor changes to wording for consistency and clarification.

III. Regulatory Procedures

A. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995,[4] the Board has reviewed the final rule and determined it does not contain or modify a collection of information subject to the PRA. The PRA applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or increases an existing burden. For purposes of the PRA, a paperwork burden may take the form of a reporting or recordkeeping requirement, both referred to as information collections. Information collected as part of an affidavit, oath, affirmation, certification, receipt, changes of address, consent, or acknowledgment, however, is not considered an information collection for purposes of the PRA.

This category is limited to those disclosures that require persons to provide or display only facts necessary to identify themselves. For example, they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. ''Nature of the instrument'' refers to a respondent's request for materials, such as publications or other information from an agency. To facilitate such requests for information from an agency, an agency may ask requesters to describe the material or information sought in detail sufficient to describe the individual desires.

The final rule implements the FOIA Improvement Act of 2016 by amending the agency's FOIA regulations. Because the only paperwork burden in this final rule relates to activities that are not considered to be information collections, NCUA has determined that this rule is exempt from the requirements of the PRA.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a rule may have on a substantial number of small credit unions (those under $100 million in assets). This final rule does not impose any requirements on federally insured credit unions. Therefore, it will not have a significant economic impact on a substantial number of small credit unions and a regulatory flexibility analysis is not required. Because this final rule would affect few, if any, small entities, the Board certifies that the final rule will

[1] 81 FR 93792 (Dec 22, 2016).

[2] 12 CFR part 792.

[3] Public Law 114–185, 130 Stat. 538.

[4] 44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1.

not have a significant economic impact on small entities.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. The final rule would not have substantial direct effects on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the executive order.

D. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

NCUA has determined that this final rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act of 1999.[5]

E. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where the Board issues a final rule as defined by Section 551 of the APA. The Board submitted the rule to the Office of Management and Budget. It determined the rule is not a ''major rule'' within the meaning of the relevant sections of SBREFA.

List of Subjects in 12 CFR Part 792

Administrative practice and procedure, Credit unions, Freedom of Information, Information, Privacy, Records, System of records.

By the National Credit Union Administration Board on June 22, 2017.

Gerard Poliquin,

Secretary of the Board.

For the reasons stated above, the National Credit Union Administration adopts the interim rule published December 22, 2016, at 81 FR 93792, as final with the following changes:

[5] Public Law 105–277, 112 Stat. 2681.

PART 792—REQUESTS FOR INFORMATION UNDER THE FREEDOM OF INFORMATION ACT AND PRIVACY ACT, AND BY SUBPOENA; SECURITY PROCEDURES FOR CLASSIFIED INFORMATION

■ 1. The authority citation for part 792 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b; 12 U.S.C. 1752a(d), 1766, 1789, 1795f; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p.235; E.O. 13526, 75 FR 707, 2009 Comp. p.298.

■ 2. In § 792.02, revise the introductory text and paragraph (d) to read as follows:

§ 792.02 What records does NCUA make available to the public for inspection and copying?

Except for records that are exempt from public disclosure under FOIA as amended (5 U.S.C. 552) or are promptly published and copies are available for purchase, NCUA routinely makes the following five types of records available for you to inspect and copy and in an electronic format:

* * * * *

(d) Copies of all records, regardless of form or format, which have been released after March 31, 1997, in response to a FOIA request and which, because of the nature of their subject matter, NCUA determines have been or are likely to become the subject of subsequent requests; or records that have been requested three (3) or more times; and

* * * * *

■ 3. In § 792.03, revise the introductory text and paragraph (c) to read as follows:

§ 792.03 How will I know which records to request?

NCUA maintains current indices providing identifying information for the public for any matter referred to in § 792.02, issued, adopted, or promulgated after July 4, 1967. The listing of material in an index is for the convenience of possible users and does not constitute a determination that all of the items listed will be disclosed. NCUA has determined that publication of the indices is unnecessary and impractical. You may obtain copies of indices by making a request to the NCUA, Office of General Counsel, 1775 Duke Street, Alexandria, VA 22314–2387, Attn: FOIA Officer or as indicated on the NCUA Web site at *www.ncua.gov.* The indices are available for public inspection and copying, provided at their duplication cost, and in an electronic format. The indices are:

* * * * *

(c) Popular FOIA Index: Records released in response to a FOIA request, that NCUA determines are likely to be the subject of subsequent requests because of the nature of their subject matter, or records that have been requested three (3) or more times. The Popular FOIA Index is available on the NCUA Web site.

■ 4. In § 792.10, revise paragraph (e) to read as follows:

§ 792.10 What will NCUA do with my request?

* * * * *

(e) Upon a determination by the appropriate Information Center to comply with your initial request for records, the records will be made promptly available to you. NCUA will also advise you of the right to seek assistance from the FOIA Public Liaison. If we notify you of a denial of your request, we will include the reason for the denial. NCUA will also advise you of the right to utilize dispute resolution services offered by the FOIA Public Liaison and the Office of Government Information Services.

* * * * *

■ 5. In § 792.11, revise paragraph (a)(5) to read as follows:

§ 792.11 What kinds of records are exempt from public disclosure?

(a) * * *

(5) Inter-agency or intra-agency memoranda or letters which would not be available by law to a private party in litigation with NCUA. This exemption preserves the existing freedom of NCUA officials and employees to engage in full and frank written or taped communications with each other and with officials and employees of other agencies. It includes, but is not limited to, inter-agency and intra-agency reports, memoranda, letters, correspondence, work papers, and minutes of meetings, as well as staff papers prepared for use within NCUA or in concert with other governmental agencies. In applying this exemption, the NCUA will not withhold records based on the deliberative process privilege if the records were created 25 years or more before the date on which the records were requested.

* * * * *

■ 6. In § 792.15, revise paragraph (b)(2) to read as follows:

§ 792.15 How long will it take to process my request?

* * * * *

(b) * * *

(2) Such alternative time period as mutually agreed by you and the Information Office, when NCUA notifies

you that the request cannot be processed in the specified time limit. In such cases, NCUA will make available its FOIA Public Liaison and notify you of the right to seek dispute resolution services from the Office of Government Information Services.

■ 7. In § 792.16, revise paragraph (c) to read as follows:

§ 792.16 What unusual circumstances can delay NCUA's response?

* * * * *

(c) If NCUA sends you an extension notice, it will also advise you that you can either limit the scope of your request so that it can be processed within the statutory time limit or agree to an alternative time frame for processing your request. In such cases, NCUA will make available its FOIA Public Liaison and notify you of the right to seek dispute resolution services from the Office of Government Information Services.

■ 8. Revise § 792.17 to read as follows:

§ 792.17 What can I do if the time limit passes and I still have not received a response?

(a) If NCUA does not comply with the time limits under § 792.15, or as extended under § 792.16, you do not have to pay search fees; requesters qualifying for free search fees will not have to pay duplication fees. However, if NCUA has extended the time limits under § 792.16 and must review more than 5,000 pages to respond to the request, NCUA may charge you search fees (or for requesters qualifying for free search fees, duplication fees), if NCUA has discussed with you via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how you could effectively limit the scope of the request.

(b) You can seek assistance from the FOIA Public Liaison or dispute resolution services from the Office of Government Information Services. You also can file suit against NCUA because you will be deemed to have exhausted your administrative remedies if NCUA fails to comply with the time limit provisions of this subpart. If NCUA can show that exceptional circumstances exist and that it is exercising due diligence in responding to your request, the court may retain jurisdiction and allow NCUA to complete its review of the records. You may have to pay search or duplication fees if a court has determined that exceptional circumstances exist and has extended the time limits for NCUA's response by a court order. In determining whether exceptional circumstances exist, the court may consider your refusal to modify the scope of your request or arrange an alternative time frame for processing after being given the opportunity to do so by NCUA, when it notifies you of the existence of unusual circumstances as set forth in § 792.16.

■ 9. In § 792.28, revise the introductory text to read as follows:

§ 792.28 What if I am not satisfied with the response I receive?

If you are not satisfied with NCUA's response to your request, you can seek dispute resolution services from the FOIA Public Liaison and the Office of Government Information Services, and you can file an administrative appeal. Your appeal must be in writing and must be filed within 90 days from receipt of the initial determination (in cases of denials of the entire request or denials of a fee waiver or reduction), or from receipt of any records being made available pursuant to the initial determination (in cases of partial denials). In the response to your initial request, the Freedom of Information Act Officer or the Inspector General (or designee), will notify you that you may appeal any adverse determination to the Office of General Counsel. The General Counsel, or designee, as set forth in this paragraph, will:

* * * * *

[FR Doc. 2017–13640 Filed 6–29–17; 8:45 am]

BILLING CODE 7535–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Parts 1024 and 1026

[Docket No. CFPB–2017–0016]

Policy Guidance on Supervisory and Enforcement Priorities Regarding Early Compliance With the 2016 Amendments to the 2013 Mortgage Rules Under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z)

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Policy guidance.

SUMMARY: The Consumer Financial Protection Bureau (Bureau) is issuing policy guidance on its supervisory and enforcement priorities regarding early compliance with the final rule it issued in August 2016 (2016 Mortgage Servicing Final Rule) amending certain of the Bureau's mortgage servicing rules.

DATES: The Bureau released this Policy Guidance on its Web site on June 27, 2017.

FOR FURTHER INFORMATION CONTACT: Joel L. Singerman, Counsel, or Laura A. Johnson, Senior Counsel, Office of Regulations, at 202–435–7700.

SUPPLEMENTARY INFORMATION:

I. Summary

On August 4, 2016, the Bureau issued the 2016 Mortgage Servicing Final Rule clarifying, revising, or amending certain of the Bureau's mortgage servicing rules.[1] Each of the changes will take effect on either Thursday, October 19, 2017, or Thursday, April 19, 2018.[2] The Bureau has heard concerns that these midweek effective dates for the 2016 Mortgage Servicing Final Rule could create operational challenges for servicers. The Bureau understands that, for many servicers, the Thursday effective dates could afford less than a full day—from the close of business overnight on each of the preceding Wednesdays—to update and test systems in order to be compliant with the 2016 amendments. If servicers do not have sufficient time to complete these tasks, their systems may be more likely to produce errors, which could expose servicers and consumers to risk. Industry participants have notified the Bureau that implementing the 2016 Mortgage Servicing Final Rule during the weekend, with early compliance beginning on the Monday before each of the respective Thursday effective dates, would address these concerns.

The Bureau understands industry's concerns and believes that, in the context of the 2016 Mortgage Servicing Final Rule, servicers and consumers are likely to benefit if servicers have the weekend immediately before each of the effective dates to update and test their systems. The Bureau does not, therefore, intend to take supervisory or enforcement action for violations of existing Regulation X or Regulation Z resulting from a servicer's compliance with the 2016 Mortgage Servicing Final Rule occurring up to three days before the applicable effective dates. For these purposes, ''up to three days before the applicable effective dates'' means, for the amendments that will take effect on Thursday, October 19, 2017, the period of Monday, October 16, through Wednesday, October 18, 2017; and, for the amendments that will take effect on Thursday, April 19, 2018, the period of Monday, April 16, through Wednesday, April 18, 2018.

[1] Amendments to the 2013 Mortgage Rules under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z), 81 FR 72160 (Oct. 19, 2016).

[2] *See id.* at 72160, 72349–50.

II. Regulatory Requirements

This Policy Guidance is a non-binding general statement of policy articulating considerations relevant to the Bureau's exercise of its supervisory and enforcement authority. It is therefore exempt from notice and comment rulemaking requirements under the Administrative Procedure Act pursuant to 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a). The Bureau has determined that this Policy Guidance does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

Dated: June 26, 2017.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2017–13799 Filed 6–29–17; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

Control Policy: End-User and End-Use Based

CFR Correction

■ In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2017, on page 498, in supplement number 4 to part 744, under United Arab Emirates, remove the entry for ''Indira Mirchandani''.

[FR Doc. 2017–13802 Filed 6–29–17; 8:45 am]

BILLING CODE 1301–00–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 111

[Docket No. USCBP–2016–0059; CBP Dec. No. 17–05]

RIN 1651–AB07

Modernization of the Customs Brokers Examination

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with changes, the amendments proposed to the U.S. Customs and Border Protection (CBP) regulations concerning the customs broker's examination provisions. Specifically, this rule transitions the examination to a computer automated customs broker examination, adjusts the dates of the examination to account for the fiscal year transition period and payment schedule requirements, and increases the examination fee to cover the cost of delivering the exam.

DATES: Effective July 31, 2017.

FOR FURTHER INFORMATION CONTACT: Julia Peterson, Chief, Broker Management Branch, Office of Trade, U.S. Customs and Border Protection, (202) 863–6601, *julia.peterson@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 641 of the Tariff Act of 1930, as amended (19 U.S.C. 1641), provides, among other things, that a person (an individual, corporation, association, or partnership) must hold a valid customs broker's license and permit in order to transact customs business on behalf of others, sets forth standards for the issuance of a broker's license and permit, and provides for disciplinary action against brokers that have engaged in specific infractions. This section also provides that an examination may be conducted to assess an applicant's qualifications for a license.

The regulations issued under the authority of section 641 are set forth in title 19 of the Code of Federal Regulations, part 111 (19 CFR part 111). Part 111 sets forth the regulations regarding, among other things, the licensing of, and granting of permits to, persons desiring to transact customs business as customs brokers. These regulations also include the qualifications required of applicants and the procedures for applying for licenses and permits, including examination procedures and requirements.

Currently, a customs broker's examination consists of a paper test booklet and a scannable answer sheet which is administered by the Office of Personnel Management (OPM). CBP supplements OPM's resources by providing CBP officials to proctor the examination and space to conduct the examination. There is a $200 fee to take the examination. This fee, which has not changed since 2000, currently does not cover the administrative costs of the paper-based examination as the costs of administering the examination have increased. At the same time that CBP is looking to update its fee to reflect the costs of administering the exam, OPM has informed CBP that it will no longer administer the paper-based examination and it is shifting all the examinations it administers to an electronic format.

On September 14, 2016, CBP published a document in the **Federal Register** (81 FR 63149) proposing to amend title 19 of the Code of Federal Regulations (''19 CFR'') to modernize the customs broker's examination provisions. Specifically, CBP proposed amending the customs broker's examination provisions, which are contained in 19 CFR part 111, to permit automation of the examination. CBP proposed removing references to the ''written'' examination to accommodate the transition from the paper and pencil format to an electronic format; and proposed removing the requirement that CBP grade the examinations to permit officials at the Office of Personnel Management (OPM) or OPM contractors to grade the examinations. CBP proposed removing the reference to ''Headquarters'' to allow CBP offices nationwide to assist in preparing the examination. CBP also proposed moving the examination dates to the fourth Monday in April and October to allow more time between the start of the federal fiscal year and the October examination date. To cover the costs of administering the examination, plus the cost of automating the examination, CBP proposed to increase the fee. CBP proposed removing the special examination provision because it was unnecessary. Finally, to better reflect CBP's organizational structure, CBP proposed updating the information on whom to contact when an applicant either would miss an examination, or would file an appeal of examination results. CBP proposed these changes to benefit both applicants and CBP. For applicants, automation would standardize the testing environment and equipment for all examinations, and provide earlier notification of test scores. For CBP, automation would provide for a more efficient use of CBP staff and administrative resources. The notice of proposed rulemaking requested public comments. The public comment period closed on November 14, 2016.

Discussion of Comments

Eight comments were received in response to the notice of proposed rulemaking.

Comment: Six commenters sought clarification about the transition from a paper and pencil format to computer automated examinations as described in

the proposed rule. Three of them requested an additional explanation of how the removal of ''written'' from the description of the examination in the proposed regulations determined the examination format. One commenter suggested replacing ''written'' with another term, such as ''multiple choice,'' to describe the exact examination format in the regulations.

CBP Response: CBP disagrees that the regulations need to define a specific form of examination. CBP is removing the term ''written'' to describe the examination from the regulation to provide flexibility in the transition from the paper and pen format to delivering the examination via computer. For that reason, CBP is not limiting the examination format by including specific parameters, such as ''multiple choice.'' CBP understands the applicants' desire for transparency on the type of question (*e.g.* multiple choice, true/false, essay) that will appear on the examination; therefore, CBP will provide guidance to the public on *CBP.gov* prior to the administration of the electronic examination.

Comment: Several commenters raised specific questions about the process of taking the new electronic examination. Commenters asked whether applicants could choose a testing site; whether applicants could bring electronic reference materials to the site, and, if not, whether they would have sufficient space to use their paper reference materials and receive scrap paper for solving problems; whether they could change their answers during the allotted time; whether they could skip questions and return to them later; and whether the computer program would track skipped questions for the examinee. Commenters also asked whether CBP would have a contingency plan for technical difficulties, whether CBP was going to test the automated examination program before requiring it nationwide, whether it would provide a practice test, when it would provide the answer key, and when it would provide the results to the applicants.

CBP Response: CBP understands the concerns about a new examination format; thus CBP will provide guidance to the public on *CBP.gov* prior to the administration of the electronic examination.

The selection of an examination location depends on the information in the application. Applicants select their business port when they register for the customs broker's examination; CBP assigns the applicants to the exam locations closest to their selected port. With the examination location notification, CBP will provide the applicant with contingency plans for system failures, power outages, and other site-related breakdowns or emergencies. The examination sites themselves will offer ample room for hard copies of reference material, and the guidance on *CBP.gov* will describe the permitted reference materials. Applicants will receive scrap paper at examination sites. The examination sites, however, will provide access to only one computer monitor per examinee: Applicants will not have access to a second monitor or be permitted to access reference materials on-line.

The electronic examination itself will allow applicants to skip answers, to return to skipped or completed answers, and to change their answers during the examination period. After the broker's examination development team completes its testing of the electronic examination, CBP will provide a link to a sample practice examination so that applicants can familiarize themselves with the format and how to navigate within the examination. The guidance CBP will provide on *CBP.gov* will include information on how and when CBP anticipates it will provide a copy of the examination and its answer key. CBP will post the examination online at *CBP.gov* after the completion of all the examinations at all examination locations. CBP will post the examination answer key on *CBP.gov* after it vets the examination results.

Comment: Several commenters questioned the examination fee increase to $390, or requested more information about the basis for the increase in the fee. They compared the new fee to other licensing fees, and the increase in the examination fee to increases resulting from inflation or changes in the cost of living since 2000; and stated that the fee would be expensive for individuals beginning their trade careers. Commenters questioned how automation could be so expensive when it would save administrative resources.

CBP Response: CBP appreciates that the fee may be expensive for some individuals but CBP disagrees that its examination fee increase is too high as it is set to cover CBP's costs to provide the exam under the new exam process. The fee is not being changed merely to adjust the existing fee for inflation, or to bring it in line with licensing fees for exams in unrelated fields, but to reflect CBP's costs of providing the exam. The Office of Personnel Management has informed CBP that it will soon no longer administer the current paper based examination. Instead, the exam will now be electronic and provided at private testing centers. While the automation itself saves money by reducing the time spent preparing and grading the exam, the need to rent testing centers with professional proctors will increase the overall exam costs. The increase in costs over time due to inflation, coupled with the need to change to an all-electronic exam administered at private testing centers, makes it necessary to increase the customs broker exam fee from $200 to $390 for CBP to recover all of its costs to administer the customs broker exam.

Comment: Commenters said that an individual's brokerage does not always reimburse for the cost of the exam and that $390 would be a large expense for individuals.

CBP Response: CBP acknowledges that not all brokerages reimburse their employees for the cost of the exam and some only reimburse their employees when they pass the exam. This is consistent with the analysis that indicates only that there is some portion of brokerages who do reimburse their employees and that there are brokers who are sole proprietors. This discussion takes place in the Regulatory Flexibility Act section of this document, which analyzes the impact on small entities. Small entities, as defined by the Regulatory Flexibility Act, includes small businesses but does not include individuals (other than sole proprietors). Therefore, the cost to individuals was not analyzed in this section. For an analysis of the costs of this rule to all parties, see the Executive Orders 13563, 12866, and 13771 and Regulatory Flexibility Act sections in this notice.

Comment: Several commenters requested additional information on what costs were covered by the fee.

CBP Response: As requested, CBP has revised the administrative costs section in the fee study to include a more detailed description of what is included in the costs for informational purposes. Exam administration costs are the costs associated with administering the customs broker license exam. CBP contracts with the U.S. Office of Personnel Management (OPM) to administer the exam. The contracted services include, but are not limited to: The development of the exam onto an electronic platform, the renting of testing locations, the providing of equipment and proctors, the grading of the exam, the mailing of individual score sheets to each examinee, and the providing to CBP of an array of exam metrics including distractor analysis and frequency distribution. The fee study documenting the proposed fee changes, entitled ''Customs Broker License Examination Fee Study,'' has

been included in the docket of this rulemaking (Docket No. USCBP–2016–0059). As stated in the fee study, there were two inputs to determining the new examination fee—the costs to both CBP and OPM and the number of examinees. The cost of administering the examination is increasing to $390 because CBP now has to hire professional proctors and rent out formal testing centers instead of using port staff to proctor the exam and port facilities to administer the exam.

Comment: Several commenters objected to eliminating the special examination provision, mentioned CBP had applied the provision in 2001, and requested that it remain, in case of extenuating circumstances or unforeseen emergencies.

CBP Response: CBP agrees and will retain the special examination provision at 19 CFR 111.13(c) with changes to reflect that the special examination will also be modernized to allow for electronic testing. In addition, CBP changed the provision to require that special examination requests be submitted to the Executive Assistant Commissioner, Office of Trade.

Comment: Although no one objected to moving the customs broker's examination dates later in April and October, several commenters suggested that neither Monday nor Friday were ideal dates for business reasons.

CBP Response: CBP agrees that moving the exam administration date to the fourth Wednesday in October and in April would be beneficial. Accordingly, CBP changed the administration date from the fourth Monday to the fourth Wednesday in 19 CFR 111.13(b).

Conclusion

Accordingly, after review of the comments and further consideration, CBP has decided to adopt as final, with the changes discussed above, and grammatical corrections, the proposed rule published in the **Federal Register** (81 FR 63149) on September 14, 2016. Specifically, the final rule will change the examination dates to the fourth Wednesday in April and October (not the fourth Monday); and, will retain the special examination provision with changes in § 111.13(c) (19 CFR 111.13(c)).

Executive Orders 13563, 12866, and 13771

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (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. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. *See* OMB's Memorandum ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017).

1. Purpose of the Rule

Customs brokers are private individuals and/or business entities (partnerships, associations or corporations) that are regulated and empowered by CBP to assist importers and exporters in meeting federal requirements governing imports and exports. Customs brokers have an enormous responsibility to their clients and to CBP that requires them to properly prepare importation and exportation documentation, file these documents timely and accurately, classify and value goods properly, pay duties and fees, and safeguard their clients' information.

CBP currently licenses brokers who meet a certain set criteria. One criterion is that each prospective broker must first pass a broker license exam. CBP's current paper-based examination method will soon no longer be available and so CBP is shifting to an all-electronic exam. The all-electronic exam has benefits to both CBP and the trade, such as a faster processing time, which lets examinees know their results more quickly and efficiently, and a significant reduction in administrative duties for CBP employees. However, administering this new electronic exam is also more expensive. Additionally, the current $200 fee does not cover the costs of the current paper exam. CBP is therefore increasing the examination fee from $200 to $390 in order to fully cover all of CBP's costs of administering the broker examination.

CBP is also changing the date of the semi-annual customs broker exam from the first Monday in October and April to the fourth Wednesday in October and April for easier administration.

2. Background

It is CBP's responsibility to ensure that only qualified individuals and business entities can perform customs business on another party's behalf. The first step in meeting the eligibility requirements for a customs broker license requires an individual to pass the customs broker license examination. Currently paper-based, the customs broker examination is an open-book examination consisting of 80 multiple-choice questions.

An individual currently must meet the following criteria in order to be eligible to take the customs broker examination:

- Be a U.S. citizen at least 18 years of age; [1]
- Not be an employee of the U.S. federal government; and
- Pay a $200 examination fee.

The customs broker examination is offered semi-annually, in April and October, and an examinee has four and a half (4.5) hours to complete it. Based on prior year exams from 2004 to 2013, CBP estimates that there will be approximately 2,600 examinees per year, or 1,300 examinees per session. Currently the broker exam is given at 50 testing locations around the country. CBP anticipates that changing the exam format from paper-based to electronic would result in no change in the number of testing locations in the country; the only change would be the type of testing location. The exam is currently administered at hotels and ports throughout the country. In the future, the exam will instead be held at privately operated formal testing locations.

Beginning in October 2017, the current paper testing option will no longer be available and the broker examination will be fully electronic. Despite the higher costs of an electronic exam, it has many favorable features which would benefit both CBP and the examinees, including shorter wait times for examinees to get their test results and a reduction in the time CBP staff

[1] Although U.S. citizens at least 18 years old may take the broker license exam, a U.S. citizen must be at least 21 years old to apply to become a licensed customs broker. An individual has three years, from the time the individual takes the customs broker exam, to apply to become a licensed customs broker.

spends on administrative matters related to the exam, such as arranging facility space for and proctoring the exam, fielding questions from examinees and mailing test result notices.

3. Costs

As discussed above, CBP currently charges a $200 fee for the customs broker license examination. This fee is used to offset the costs associated with providing the services necessary to operate the customs broker license examination. Based on a recently completed fee study entitled, ''Customs Broker License Examination Fee Study,'' CBP has determined that these fees are no longer sufficient to cover its costs.[2] Currently, examinees go to either a port or to a rented event space in a hotel to take the paper exam with a 35-page test booklet and a scannable answer sheet, which must subsequently be collected and graded. The new all-electronic version of the exam will be administered entirely on a computer where the examinees answer the questions directly on the screen and the exam is graded automatically. As the electronic exam uses all private facilities with professional proctors, this automated method will be more expensive than the paper exam. Furthermore, the current fee is not enough to cover even the current costs of administering the exam. Exam administration costs include the development of the exam in an electronic platform, the renting of testing locations, the providing of equipment and proctors, the grading of the exam, the mailing of individual score sheets to each examinee, and the providing to CBP of an array of exam metrics including distractor analysis and frequency distribution. As stated above, the current $200 fee has not been changed since 2000. According to data provided by CBP's Broker Management Branch, administrative and testing costs have increased since the fee was last changed. This increase in administrative fees coupled with switching to an all-electronic exam administered at private testing centers, makes it necessary to increase the customs broker exam fee from $200 to $390 for CBP to recover all of its costs to administer the customs broker exam.

CBP has determined that the fee of $390 is necessary to recover the costs associated with administering the customs broker license examination once the exam is made electronic. The customs broker examination is an established service provided by CBP that already requires a fee payment. Absent this rule, CBP would be operating the exam at a loss and this fee is intended to offset that loss. As such, a change in the fee is not a net cost to society, but rather a transfer payment from test takers to the government.[3] CBP does recognize, however, that the fee change may have a distributional impact on prospective customs brokers. In order to inform stakeholders of all potential effects of the final rule, CBP has analyzed the distributional effects of the final rule in section ''5. Distributional Impact.''

4. Benefits

As discussed above, CBP is increasing the customs broker license examination fee from $200 to $390. The broker exam fee was last changed in 2000 when it was reduced from $300 to the current fee of $200. The lower cost paper-based examination that is currently being administered is being replaced by an all-electronic exam in an effort to fully modernize the customs broker testing procedure. This fee increase will allow CBP to fully recover all of its costs, including those to provide a fully electronic version of the customs broker examination beginning in October 2017. As discussed above, the fee increase is neither a cost nor a benefit of this rule since the broker exam fee is already an established fee. Thus, the fee increase is considered a transfer payment. As stated above, in order to inform stakeholders of all potential effects of the final rule, CBP has analyzed the distributional effects of the final rule in section ''5. Distributional Impact.''

In addition to increasing the examination fee, CBP is changing the date the examination is given from the first Monday in October and April to the fourth Wednesday in October and April. Administering the examination on the first Monday in October is administratively difficult because it is too close to the conclusion of the Federal Government's fiscal year at the end of September. With this rule's changes, CBP and the examinees will benefit through greater predictability in years where federal budgets are uncertain.

5. Distributional Impact

Under the final rule, the customs broker license examination fee will increase from $200 to $390 in order for CBP to fully recover all of its costs to administer the broker examination. As noted above, these costs are increasing due to a shift in the administration of the exam that will go into effect beginning with the October 2017 exam.

The customs broker license examination fee will cost individuals an additional $190 when they register to take the customs broker license examination. As discussed above, CBP estimates that there will be 2,600 examinees per year (1,300 per session) who will take the customs broker license examination. Using this estimate and the additional cost that each examinee will incur, CBP estimates that the fee increase will result in a transfer payment to the government of approximately $494,000 per year (2,600 examinees per year * $190 proposed fee increase = $494,000).

Regulatory Flexibility Act

This section examines the impact of the rule on small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA). A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

The final rule will apply to all prospective brokers who take the broker exam. The fee is paid by the individual taking the broker exam and individuals are not considered small entities under the Regulatory Flexibility Act. However, some of these individuals are sole proprietors or may be reimbursed for this expense by their brokerage, so we consider the impact on these entities. The U.S. Census Bureau categorizes customs brokers (as well as freight forwarders and marine shipping agents) under the North American Industry Classification (NAICS) code 488510. As shown in Exhibit 1 below, approximately 96 percent of business entities in this NAICS code are small. As this rule will affect any prospective broker or his/her employer, regardless of its size, this rule has an impact on a substantial number of small entities.

The direct impact of this rule on each individual customs broker examinee, or his/her employer, is the fee increase of $190. To assess whether this is a significant impact, we examine the annual revenue for customs brokers. The U.S. Census Bureau categorizes customs brokers under the NAICS code 488510. In addition to customs brokers, this NAICS code also includes freight

[2] The fee study is included in the docket of this rulemaking (Docket No. USCBP–2016–0059).

[3] Transfer payments are monetary payments from one group to another that do not affect total resources available to society. See OMB Circular A–4.

forwarders and marine shipping agents.[4] The Small Business Administration (SBA) publishes size standards that determine the criteria for being considered a small entity for the purposes of this analysis. The SBA considers a business entity classified under the 488510 NAICS code as small if it has less than $15 million in annual receipts. We obtained the number of firms in each revenue category provided by the U.S. Census Bureau (see Exhibit 1 below). To estimate the average revenue of all firms under this NAICS code, we first assumed that each firm in each revenue category had receipts of the midpoint of the range. For example, we assumed that the 4,354 firms with annual receipts of between $100,000 and $499,000 had average receipts of $300,000. We then used the number of firms in each category to calculate the weighted average revenue across all small firms. Using this method, we estimate that the weighted average revenue for small businesses in this NAICS code is $1,496,197. The $190 increase in the broker exam fee, then, represents 0.01 percent of the weighted average annual revenue for brokers. CBP does not consider 0.01 percent of revenue per exam to be a significant impact. Accordingly, CBP certifies that this rule does not have a significant economic impact on a substantial number of small entities.

EXHIBIT 1—BUSINESS ENTITY DATA FOR NAICS CODE 488510

Annual receipts ($) (Midpoint)	Number of firms	Small
<100,000 (50,000)	1,834	Yes.
100,000–499,999 (300,000)	4,354	Yes.
500,000–999,999 (750,000)	2,040	Yes.
1,000,000–2,499,999 (1,750,000)	2,300	Yes.
2,500,000–4,999,999 (3,750,000)	1,087	Yes.
5,000,000–7,499,999 (6,250,000)	427	Yes.
7,500,000–9,999,999 (8,750,000)	242	Yes.
10,000,000–14,999,999 (12,500,000)	233	Yes.
>15,000,000	548	No.
Total	13,065	96 Percent are Small (12,517/13,065).

Source: U.S. Census Bureau.

Signing Authority

This document is being issued in accordance with 19 CFR 0.2(a), which provides that the authority of the Secretary of the Treasury with respect to CBP regulations that are not related to customs revenue functions was transferred to the Secretary of Homeland Security pursuant to section 403(l) of the Homeland Security Act of 2002. Accordingly, this final rule to amend such regulations may be signed by the Secretary of Homeland Security (or his delegate).

List of Subjects in 19 CFR Part 111

Administrative practice and procedure, Brokers, Customs duties and inspection, Penalties, Reporting and recordkeeping requirements.

Amendments to the CBP Regulations

For the reasons given above, part 111 of title 19 of the Code of Federal Regulations (19 CFR part 111) is amended as set forth below:

PART 111—CUSTOMS BROKERS

■ 1. The authority citation for part 111 continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 1641.

Section 111.3 also issued under 19 U.S.C. 1484, 1498;

Section 111.96 also issued under 19 U.S.C. 58c, 31 U.S.C. 9701.

§ 111.11 [Amended]

■ 2. In § 111.11, paragraph (a)(4) is amended by removing the words ''a written'' and adding in its place the word ''an''.

§ 111.12 [Amended]

■ 3. In § 111.12, paragraph (a) is amended by removing the word ''written'' from the two places that it appears in the fifth and sixth sentences.

§ 111.13 [Amended]

■ 4. In § 111.13:

■ a. The section heading is revised;

■ b. Paragraph (a) is amended by:

■ 1. Removing the word ''written'' in the first sentence;

■ 2. Removing the words ''and graded at'' in the second sentence and adding in their place the word ''by''; and

■ 3. Removing the phrase ''Headquarters, Washington, DC'' from the second sentence;

■ c. Paragraphs (b) through (d) and (f) are revised.

The revisions read as follows:

§ 111.13 Examination for individual license.

* * * * *

(b) *Basic requirements, date, and place of examination.* In order to be eligible to take the examination, an individual must on the date of examination be a citizen of the United States who has attained the age of 18 years and who is not an officer or employee of the United States Government. CBP will publish a notice announcing each examination on its Web site. Examinations will be given on the fourth Wednesday in April and October unless the regularly scheduled examination date conflicts with a national holiday, religious observance, or other foreseeable event and the agency publishes in the **Federal Register** an appropriate notice of a change in the examination date. An individual who intends to take the examination must complete the electronic application at least 30 calendar days prior to the scheduled examination date and must remit the $390 examination fee prescribed in § 111.96(a) at that time. CBP will give notice of the exact time and place for the examination.

(c) *Special examination.* If a partnership, association, or corporation loses the required member or officer

[4] *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=488510&search=2012%20NAICS%20Search.*

having an individual broker's license (see § 111.11(b) and (c)(2)) and its license would be revoked by operation of law under the provisions of 19 U.S.C. 1641(b)(5) and § 111.45(a) before the next scheduled examination, CBP may authorize a special examination for a prospective applicant for an individual license who would serve as the required licensed member or officer. CBP may also authorize a special examination for an individual for purposes of continuing the business of a sole proprietorship broker. A special examination for an individual may also be authorized by CBP if a brokerage firm loses the individual broker who was exercising responsible supervision and control over an office in another district (see § 111.19(d)) and the permit for that additional district would be revoked by operation of law under the provisions of 19 U.S.C. 1641(c)(3) and § 111.45(b) before the next scheduled examination. A request for a special examination must be submitted to the Executive Assistant Commissioner, Office of Trade, in writing and must describe the circumstances giving rise to the need for the examination. If the request is granted, the Executive Assistant Commissioner, Office of Trade or his/her designee, will notify the prospective examinee of the exact time and place for the examination. If the individual attains a passing grade on the special examination, the application for the license may be submitted in accordance with § 111.12. The examinee will be responsible for all additional costs incurred by CBP in preparing and administering the special examination that exceed the $390 examination fee prescribed in § 111.96(a), and those additional costs must be reimbursed to CBP before the examination is given.

(d) *Failure to appear for examination.* If a prospective examinee advises the Office of Trade at the Headquarters of U.S. Customs and Border Protection, Attn: Broker Management Branch, electronically in a manner specified by CBP at least 2 working days prior to the date of a regularly scheduled examination that he will not appear for the examination, CBP will refund the $390 examination fee referred to in paragraph (b) of this section. No refund of the examination fee or additional reimbursed costs will be made in the case of a special written examination provided for under paragraph (c) of this section.

* * * * *

(f) *Appeal of failing grade on examination.* If an examinee fails to attain a passing grade on the examination taken under this section, the examinee may challenge that result by filing a written appeal with the Office of Trade at the Headquarters of U.S. Customs and Border Protection, Attn: Broker Management Branch, within 60 calendar days after the date of the written notice provided for in paragraph (e) of this section. CBP will provide to the examinee written notice of the decision on the appeal. If the CBP decision on the appeal affirms the result of the examination, the examinee may request review of the decision on the appeal by writing to the Executive Assistant Commissioner, Office of Trade, U.S. Customs and Border Protection, within 60 calendar days after the date of the notice on that decision.

§ 111.96 [Amended]

■ 5. In § 111.96:

■ a. Paragraph (a) is amended by removing the word ''written'' from the second sentence and removing the phrase ''$200 examination fee'' in the second sentence and adding in its place the phrase ''$390 examination fee''; and

■ b. Paragraph (e) is amended by removing the words ''United States Customs Service'' and adding in their place the words ''U.S. Customs and Border Protection, or paid by other CBP-approved payment method''.

Dated: June 27, 2017.

Elaine C. Duke,

Deputy Secretary.

[FR Doc. 2017–13829 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9808]

RIN 1545–BL17
RIN 1545–BN74

Regulations Regarding Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons, Information Reporting and Backup Withholding on Payments Made to Certain U.S. Persons, and Portfolio Interest Treatment; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9808), which were published in the **Federal Register** on Friday, January 6, 2017 (82 FR 2046). These regulations are related to withholding of tax on certain U.S. source income paid to foreign persons, information reporting and backup withholding with respect to payments made to certain U.S. persons, and portfolio interest paid to nonresident alien individuals and foreign corporations.

DATES:

Effective Date: These corrections are effective June 30, 2017.

Applicability Date: The corrections to §§ 1.1441–0; 1.1441–1(b)(7)(ii)(B), (e)(3)(iv)(B) and (C), (e)(4)(ii)(B)(*11*), (e)(4)(ix)(D), (e)(5)(ii) through (e)(5)(ii)(B), (e)(5)(ii)(D) through (e)(5)(v)(B)(*3*), (e)(5)(v)(B)(*5*) through (e)(5)(v)(D), and (f) through (f)(4); 1.1441–1T; 1.1441–3(d)(1); 1.1441–4; 1.6045–1(m)(2)(ii) and (n)(12)(ii); and 1.6049–5(c)(1) through (c)(4) are applicable on January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Nancy Lee, (202) 317–6942 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections are §§ 1.1441–0, 1.1441–1, 1.1441–1T, 1.1441–3, 1.1441–4, 1.6045–1, and 1.6049–5, promulgated under sections 1441, 6045, 6049, and 7805 of the Internal Revenue Code. These regulations affect persons making payments of U.S. source income to foreign persons and persons making payments to certain U.S. persons subject to reporting and backup withholding.

Need for Correction

As published, the final regulations contain a number of items that need to be corrected or clarified. Several portions of TD 9808 could not be incorporated due to inaccurate amendatory instructions. Most of the correcting amendments to TD 9808 are needed to clarify or correct the results of these inaccurate amendatory instructions. The correcting amendments also include the addition, deletion, or modification of regulatory language to clarify the relevant provisions to meet their intended purposes, specifically to make a conforming change to the entry in the table of contents (§ 1.1441–0) for § 1.1441–1(e)(4)(ix); to correct typographical errors in §§ 1.1441–1(e)(4)(ix)(D), 1.1441–1T(c)(3)(ii), and 1.1441–3(d)(1); to clarify that allowances for electronic signatures in § 1.1441–1T(e)(4)(i)(B) and use of third party repository in § 1.1441–1T(e)(4)(iv)(E) are limited to Forms W–8; to remove an obsolete cross-reference

to § 1.1441–4(h); and to return § 1.6045–1(m)(2)(ii) and (n)(12)(ii) to the way those provisions read prior to unnecessary revisions in TD 9808.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.1441–0 is amended by adding an entry for § 1.1441–1(e)(4)(viii)(C); revising the entries for § 1.1441–1(e)(4)(ix), (e)(5)(v)(A), (f), and (f)(2); and removing the entries for § 1.1441–1(f)(2)(i) and (ii).

The addition and revisions read as follows:

§ 1.1441–0 Outline of regulation provisions for section 1441.

* * * * *

§ 1.1441–1 Requirement for the deduction and withholding of tax on payments to foreign persons.

* * * * *

(e) * * *

(4) * * *

(viii) * * *

(C) Reliance on a prior version of a withholding certificate.

(ix) Certificates to be furnished to withholding agent for each obligation unless exception applies.

* * * * *

(5) * * *

(v) * * *

(A) In general.

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(f) Effective/applicability date.

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(2) Lack of documentation for past years.

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■ **Par. 3.** Section 1.1441–1 is amended by:

■ 1. Adding paragraph (b)(7)(ii)(B);

■ 2. Adding paragraphs (e)(3)(iv)(B) and (C);

■ 3. Revising paragraph (e)(4)(ii)(B)(*11*);

■ 4. Revising the last sentence of paragraph (e)(4)(ix)(D);

■ 5. Revising paragraphs (e)(5)(ii) introductory text through (e)(5)(ii)(B);

■ 6. Removing paragraph (e)(5)(ii)(C) and redesignating paragraph (e)(5)(ii)(D) as new paragraph (e)(5)(ii)(C);

■ 7. Adding new paragraph (e)(5)(ii)(D) and removing paragraph (e)(5)(ii)(E);

■ 8. Revising paragraphs (e)(5)(iii) through (e)(5)(v)(B)(*3*);

■ 9. Adding paragraph (e)(5)(v)(B)(*5*) through (e)(5)(v)(D); and

■ 10. Revising the heading of paragraph (f), and paragraphs (f)(1) through (4).

The addition and revisions read as follows:

§ 1.1441–1 Requirement for the deduction and withholding of tax on payments to foreign persons.

* * * * *

(b) * * *

(7) * * *

(ii) * * *

(B) [Reserved]. For further guidance, see § 1.1441–1T(b)(7)(ii)(B).

* * * * *

(e) * * *

(3) * * *

(iv) * * *

(B) *General requirements.* A withholding statement must be provided prior to the payment of a reportable amount and must contain the information specified in paragraph (e)(3)(iv)(C) of this section. The statement must be updated as often as required to keep the information in the withholding statement correct prior to each subsequent payment. The withholding statement forms an integral part of the withholding certificate provided under paragraph (e)(3)(iii) of this section, and the penalties of perjury statement provided on the withholding certificate shall apply to the withholding statement. The withholding statement may be provided in any manner the nonqualified intermediary and the withholding agent mutually agree, including electronically. If the withholding statement is provided electronically as part of a system established by the withholding agent or nonqualified intermediary to provide the statement, however, there must be sufficient safeguards to ensure that the information received by the withholding agent is the information sent by the nonqualified intermediary and all occasions of user access that result in the submission or modification of the withholding statement information must be recorded. In addition, the electronic system must be capable of providing a hard copy of all withholding statements provided by the nonqualified intermediary. A withholding statement may otherwise be transmitted by a nonqualified intermediary via email or facsimile to a withholding agent under the requirements specified in paragraph (e)(4)(iv)(D) of this section (substituting the term withholding statement for the term Form W–8 or the term document, as applicable). A withholding agent will be liable for tax, interest, and penalties in accordance with paragraph (b)(7) of this section to the extent it does not follow the presumption rules of paragraph (b)(3) of this section or §§ 1.1441–5(d) and (e)(6), and 1.6049–5(d) for any payment of a reportable amount, or portion thereof, for which it does not have a valid withholding statement prior to making a payment. A withholding agent may not treat as valid an allocation of a payment to a chapter 4 withholding rate pool of U.S. payees described in paragraph (e)(3)(iv)(A) of this section or an allocation of a payment to a chapter 4 withholding rate pool of recalcitrant account holders described in paragraph (e)(3)(iv)(C)(*2*) of this section unless the withholding agent identifies the nonqualified intermediary maintaining the account (as described in § 1.1471–5(b)(5)) as a participating FFI (including a reporting Model 2 FFI) or registered deemed-compliant FFI (including a reporting Model 1 FFI) by applying the rules of § 1.1471–3(d)(4). Additionally, in the case of a withholdable payment that is an amount subject to withholding made on or after April 1, 2017, a withholding agent may not treat as valid an allocation of the payment to a chapter 4 withholding rate pool of U.S. payees unless the nonqualified intermediary identifies the pool of U.S. payees as one described in § 1.1471–3(c)(3)(iii)(B)(*2*)(*iii*) (or by describing such payees consistent with the description provided in § 1.1471–3(c)(3)(ii)(B)(*2*)(*iii*)).

(C) *Content of withholding statement.* The withholding statement provided by a nonqualified intermediary must contain the information required by this paragraph (e)(3)(iv)(C).

(*1*) *In general.* Except as otherwise provided by paragraph (e)(3)(iv)(C)(*2*) and (*3*) of this section), the withholding statement provided by a nonqualified intermediary must contain the information required by this paragraph (e)(3)(iv)(C)(*1*).

(*i*) Except as otherwise provided in (e)(3)(iv)(A) of this section (which excludes reporting of information with respect to certain U.S. persons on the withholding statement), the withholding statement must contain the name, address, TIN (if any), and the type of documentation (documentary evidence, Form W–9, or type of Form W–8) for every person from whom documentation has been received by the nonqualified intermediary and provided to the withholding agent and whether that person is a U.S. exempt recipient, a U.S. non-exempt recipient, or a foreign person. See paragraphs (c)(2), (20), and

(21) of this section for the definitions of foreign person, U.S. exempt recipient, and U.S. non-exempt recipient. In the case of a foreign person, the statement must indicate whether the foreign person is a beneficial owner or an intermediary, flow-through entity, U.S. branch, or territory financial institution described in paragraph (b)(2)(iv) of this section and include the type of recipient, based on recipient codes applicable for chapter 3 purposes used for filing Forms 1042–S, if the foreign person is a recipient as defined in § 1.1461–1(c)(1)(ii).

(*ii*) The withholding statement must allocate each payment, by income type, to every payee required to be reported on the withholding statement for whom documentation has been provided (including U.S. exempt recipients except as provided in paragraph (e)(3)(iv)(A) of this section). Any payment that cannot be reliably associated with valid documentation from a payee shall be treated as made to an unknown payee in accordance with the presumption rules of paragraph (b) of this section and §§ 1.1441–5(d) and (e)(6) and 1.6049–5(d). For this purpose, a type of income is determined by the types of income required to be reported on Forms 1042–S or 1099, as appropriate. Notwithstanding the preceding sentence, deposit interest (including original issue discount) described in section 871(i)(2)(A) or 881(d) and interest or original issue discount on short-term obligations as described in section 871(g)(1)(B) or 881(e) is only required to be allocated to the extent it is required to be reported on Form 1099 or Form 1042–S. See § 1.6049–8 (regarding reporting of bank deposit interest to certain foreign persons). If a payee receives income through another nonqualified intermediary, flow-through entity, or U.S. branch or territory financial institution described in paragraph (e)(2)(iv) of this section (other than a U.S. branch or territory financial institution treated as a U.S. person), the withholding statement must also state, with respect to the payee, the name, address, and TIN, if known, of the other nonqualified intermediary or U.S. branch from which the payee directly receives the payment or the flow-through entity in which the payee has a direct ownership interest. If another nonqualified intermediary, flow-through entity, or U.S. branch fails to allocate a payment, the name of the nonqualified intermediary, flow-through entity, or U.S. branch that failed to allocate the payment shall be provided with respect to such payment.

(*iii*) If a payee is identified as a foreign person, the nonqualified intermediary must specify the rate of withholding to which the payee is subject, the payee's country of residence and, if a reduced rate of withholding is claimed, the basis for that reduced rate (*e.g.,* treaty benefit, portfolio interest, exempt under section 501(c)(3), 892, or 895). The allocation statement must also include the TINs of those foreign persons for whom such a number is required under paragraph (e)(4)(vii) of this section or § 1.1441–6(b)(1) (regarding claims for treaty benefits for which a TIN is provided unless a foreign tax identifying number described in § 1.1441–6(b)(1) is provided). In the case of a claim of treaty benefits, the nonqualified intermediary's withholding statement must also state whether the limitation on benefits and section 894 statements required by § 1.1441–6(c)(5) have been provided, if required, in the beneficial owner's Form W–8 or associated with such owner's documentary evidence.

(*iv*) The withholding statement must also contain any other information the withholding agent reasonably requests in order to fulfill its obligations under chapter 3 and chapter 61 of the Code, and section 3406.

(*2*) *Nonqualified intermediary withholding statement for withholdable payments.* This paragraph (e)(3)(iv)(C)(*2*) modifies the requirements of a withholding statement described in paragraph (e)(3)(iv)(C)(*1*) of this section that is provided by a nonqualified intermediary with respect to a reportable amount that is a withholdable payment. For such a payment, the requirements applicable to a withholding statement described in paragraph (e)(3)(iv)(A) through (e)(3)(iv)(C)(*1*) of this section shall apply, except that—

(*i*) The withholding statement must include the chapter 4 status (using the applicable status code used for filing Form 1042–S) and GIIN (when required for chapter 4 purposes under § 1.1471–3(d)) of each other intermediary or flow-through entity that is a foreign person and that receives the payment, excluding an intermediary or flow-through entity that is an account holder of or interest holder in a withholding foreign partnership, withholding foreign trust, or intermediary acting as a qualified intermediary for the payment;

(*ii*) If the nonqualified intermediary that is a participating FFI or registered deemed-compliant FFI provides a withholding statement described in § 1.1471–3(c)(3)(iii)(B)(*2*) (describing an FFI withholding statement), the withholding statement may include chapter 4 withholding rate pools with respect to the portions of the payment allocated to nonparticipating FFIs and recalcitrant account holders (to the extent permitted on an FFI withholding statement described in that paragraph) in lieu of providing specific payee information with respect to such persons on the statement (including persons subject to chapter 4 withholding) as described in paragraph (e)(3)(iv)(C)(*1*) of this section;

(*iii*) If the nonqualified intermediary provides a withholding statement described in § 1.1471–3(c)(3)(iii)(B)(*3*) (describing a chapter 4 withholding statement), the withholding statement may include chapter 4 withholding rate pools with respect to the portions of the payment allocated to nonparticipating FFIs; and

(*iv*) For a payment allocated to a payee that is a foreign person (other than a person included in a chapter 4 withholding rate pool described in paragraphs (e)(3)(iv)(C)(*2*)(*ii*) and (*iii*) of this section) that is reported on a withholding statement described in § 1.1471–3(c)(3)(iii)(B)(*2*) or (*3*), the withholding statement must include the chapter 4 status of the payee (unless an exception applies for purposes of providing such status under chapter 4) and, for a payee other than an individual, the recipient code for chapter 4 purposes used for filing Form 1042–S; and

(*v*) To the extent that a withholdable payment is not reportable on a Form 1042–S, Form 1099 under the rules of chapter 61, or Form 8966 ''FATCA Report,'' no allocation of the payment is required on the withholding statement.

(*3*) [Reserved]. For further guidance, see § 1.1441–1T(e)(3)(iv)(C)(*3*).

(*4*) *Example.* This example illustrates the principles of paragraph (e)(3)(iv)(C) of this section. WA makes a withholdable payment of U.S. source dividends to NQI, a nonqualified intermediary. NQI provides WA with a valid intermediary withholding certificate under paragraph (e)(3)(iii) of this section that includes NQI's certification of its status for chapter 4 purposes as a participating FFI. NQI provides a withholding statement on which NQI allocates 20% of the payment to a chapter 4 withholding rate pool of recalcitrant account holders of NQI for purposes of chapter 4 and allocates 80% of the payment equally to A and B, individuals that are account holders of NQI. NQI also provides WA with valid beneficial owner withholding certificates from A and B establishing their status as foreign persons entitled to a 15% rate of withholding under an applicable income tax treaty. Because NQI has certified its status as a participating FFI, withholding under chapter 4 is not required with respect to NQI. See § 1.1471–2(a)(4). Based on the documentation NQI provided to WA with respect to A and B, WA can reliably associate

the payment with valid documentation on the portion of the payment allocated to them and, because the payment is a withholdable payment, may rely on the allocation of the payment for NQI's recalcitrant account holders in a chapter 4 withholding rate pool in lieu of payee information with respect to such account holders. See paragraph (e)(3)(iv)(C)(*2*) of this section for the special rules for a withholding statement provided by a nonqualified intermediary for a withholdable payment. Also see § 1.1471–2(a) for WA's withholding requirements under chapter 4 with respect to the portion of the payment allocated to NQI's recalcitrant account holders and § 1.1441–3(a)(2) for coordinating withholding under chapter 3 for payments to which withholding is applied under chapter 4.

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(4) * * *

(ii) * * *

(B) * * *

(*11*) Documentary evidence that is not generally renewed or amended (such as a certificate of incorporation).

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(ix) * * *

(D) * * * See § 1.1471–3(c)(9)(v) for a similar reliance rule that applies for purposes of chapter 4.

(5) * * *

(ii) *Definition of qualified intermediary.* With respect to a payment to a foreign person, the term qualified intermediary means a person that is a party to a withholding agreement with the IRS where such person is—

(A) A foreign financial institution that is a participating FFI (including a reporting Model 2 FFI), a registered deemed-compliant FFI (including a reporting Model 1 FFI), an FFI treated as a deemed-compliant FFI under an applicable IGA that is subject to due diligence and reporting requirements with respect to its U.S. accounts similar to those applicable to a registered deemed-compliant FFI under § 1.1471–5(f)(1), excluding a U.S. branch of any of the foregoing entities, or any other category of FFI identified in a qualified intermediary withholding agreement as eligible to act as a qualified intermediary;

(B) A foreign branch or office of a U.S. financial institution or a foreign branch or office of a U.S. clearing organization that is either a reporting Model 1 FFI or agrees to the reporting requirements applicable to a participating FFI with respect to its U.S. accounts;

* * * * *

(D) Any other person acceptable to the IRS.

(iii) *Withholding agreement*—(A) *In general.* The IRS may, upon request, enter into a withholding agreement with a foreign person described in paragraph (e)(5)(ii) of this section pursuant to such procedures as the IRS may prescribe in published guidance (see § 601.601(d)(2) of this chapter). Under the withholding agreement, a qualified intermediary shall generally be subject to the applicable withholding and reporting provisions applicable to withholding agents and payors under chapters 3, 4, and 61 of the Code, section 3406, the regulations under those provisions, and other withholding provisions of the Code, except to the extent provided under the agreement.

(B) *Terms of the withholding agreement.* The withholding agreement shall specify the obligations of the qualified intermediary under chapters 3 and 4 including, for a qualified intermediary that is an FFI, the documentation, withholding, and reporting obligations required of a participating FFI or registered deemed-compliant FFI (including a reporting Model 1 FFI as defined in § 1.1471–1(b)(114)) with respect to each branch of the qualified intermediary other than a U.S. branch that is treated as a U.S. person under paragraph (b)(2)(iv)(A) of this section. The withholding agreement will specify the type of certifications and documentation upon which the qualified intermediary may rely to ascertain the classification (*e.g.,* corporation or partnership), status (*i.e.,* U.S. or foreign and chapter 4 status) of beneficial owners and payees who receive reportable amounts, reportable payments, and withholdable payments collected by the qualified intermediary for purposes of chapters 3, 4, and 61, section 3406, and, if necessary, entitlement to the benefits of a reduced rate under an income tax treaty. The withholding agreement shall specify if, and to what extent, the qualified intermediary may assume primary withholding responsibility in accordance with paragraph (e)(5)(iv) of this section. It shall also specify the extent to which applicable return filing and information reporting requirements are modified so that, in appropriate cases, the qualified intermediary may report payments to the IRS on an aggregated basis, without having to disclose the identity of beneficial owners and payees. However, the qualified intermediary may be required to provide to the IRS the name and address of those foreign customers who benefit from a reduced rate under an income tax treaty pursuant to the withholding agreement for purposes of verifying entitlement to such benefits, particularly under an applicable limitation on benefits provision. Under the withholding agreement, a qualified intermediary may agree to act as an acceptance agent to perform the duties described in § 301.6109–1(d)(3)(iv)(A) of this chapter. The withholding agreement may specify the manner in which applicable procedures for adjustments for underwithholding and overwithholding, including refund procedures, apply to qualified intermediaries and the extent to which applicable procedures may be modified. In particular, a withholding agreement may allow a qualified intermediary to claim refunds of overwithheld amounts. In addition, the withholding agreement shall specify the manner in which the IRS will verify compliance with the agreement, including the time and manner for which a qualified intermediary will be required to certify to the IRS regarding its compliance with the withholding agreement (including its performance of a periodic review) and the types of information required to be disclosed as part of the certification. In appropriate cases, the IRS may require review procedures be performed by an approved reviewer (in addition to those performed as part of the periodic review) and may conduct a review of the reviewer's findings. The withholding agreement may include provisions for the assessment and collection of tax in the event that failure to comply with the terms of the withholding agreement results in the failure by the withholding agent or the qualified intermediary to withhold and deposit the required amount of tax. Further, the withholding agreement may specify the procedures by which amounts withheld are to be deposited, if different from the deposit procedures under the Code and applicable regulations. To determine whether to enter a withholding agreement and the terms of any particular withholding agreement, the IRS will consider the type of local know-your-customer laws and practices to which the entity is subject (if the entity is an FFI), as well as the extent and nature of supervisory and regulatory control exercised under the laws of the foreign country over the foreign entity.

(iv) *Assignment of primary withholding responsibility.* Any person (whether a U.S. person or a foreign person) who meets the definition of a withholding agent under § 1.1441–7(a) (for payments subject to chapter 3 withholding) and § 1.1473–1(d) (for withholdable payments) is required to withhold and deposit any amount withheld under §§ 1.1461–1(a) and 1.1474–1(b) and to make the returns prescribed by §§ 1.1461–1(b) and (c), and by 1.1474–1(c), and (d). Under its qualified intermediary withholding

agreement, a qualified intermediary may, however, inform a withholding agent from which it receives a payment that it will assume the primary obligation to withhold, deposit, and report amounts under chapters 3 and 4 of the Code and/or under chapter 61 and section 3406 of the Code. For assuming withholding obligations as described in the previous sentence, a qualified intermediary that assumes primary withholding responsibility for payments made to an account under chapter 3 is also required to assume primary withholding responsibility under chapter 4 for payments made to the account that are withholdable payments. Additionally, a qualified intermediary may represent that it assumes chapter 61 reporting and section 3406 obligations for a payment when the qualified intermediary meets the requirements of § 1.6049–4(c)(4)(i) or (ii) for the payment. If a withholding agent makes a payment of an amount subject to withholding under chapter 3, a reportable payment (as defined in section 3406(b)), or a withholdable payment to a qualified intermediary that represents to the withholding agent that it has assumed primary withholding responsibility for the payment, the withholding agent is not required to withhold on the payment. The withholding agent is not required to determine that the qualified intermediary actually performs its primary withholding responsibilities. A qualified intermediary that assumes primary withholding responsibility under chapters 3 and 4 or primary reporting and backup withholding responsibility under chapter 61 and section 3406 is not required to assume primary withholding responsibility for all accounts it has with a withholding agent but must assume primary withholding responsibility for all payments made to any one account that it has with the withholding agent.

(v) *Withholding statement*—(A) *In general.* A qualified intermediary must provide each withholding agent from which it receives reportable amounts as a qualified intermediary with a written statement (the withholding statement) containing the information specified in paragraph (e)(5)(v)(B) of this section. A withholding statement is not required, however, if all of the information a withholding agent needs to fulfill its withholding and reporting requirements is contained in the withholding certificate. The qualified intermediary withholding agreement will require the qualified intermediary to include information in its withholding statement relating to withholdable payments for purposes of withholding under chapter 4 as described in paragraph (e)(5)(v)(C)(*2*) of this section. The withholding statement forms an integral part of the qualified intermediary's qualified intermediary withholding certificate, and the penalties of perjury statement provided on the withholding certificate shall apply to the withholding statement as well. The withholding statement may be provided in any manner, and in any form, to which qualified intermediary and the withholding agent mutually agree, including electronically. If the withholding statement is provided electronically, the statement must satisfy the requirements described in paragraph (e)(3)(iv) of this section (applicable to a withholding statement provided by a nonqualified intermediary). The withholding statement shall be updated as often as necessary for the withholding agent to meet its reporting and withholding obligations under chapters 3, 4, and 61 and section 3406. For purposes of this section, a withholding agent will be liable for tax, interest, and penalties in accordance with paragraph (b)(7) of this section to the extent it does not follow the presumption rules of paragraph (b)(3) of this section, §§ 1.1441–5(d) and (e)(6), and 1.6049–5(d) for a payment, or portion thereof, for which it does not have a valid withholding statement prior to making a payment.

(B) *Content of withholding statement.* The withholding statement must contain sufficient information for a withholding agent to apply the correct rate of withholding on payments from the accounts identified on the statement and to properly report such payments on Forms 1042–S and Forms 1099, as applicable. The withholding statement must—

(*1*) Designate those accounts for which the qualified intermediary acts as a qualified intermediary;

(*2*) Designate those accounts for which qualified intermediary assumes primary withholding responsibility under chapter 3 and chapter 4 of the Code and/or primary reporting and backup withholding responsibility under chapter 61 and section 3406;

(*3*) If applicable, designate those accounts for which the qualified intermediary is acting as a qualified securities lender with respect to a substitute dividend paid in a securities lending or similar transaction;

* * * * *

(*5*) Provide information regarding withholding rate pools, as described in paragraph (e)(5)(v)(C) of this section.

(C) *Withholding rate pools*—(*1*) *In general.* Except to the extent it has assumed both primary withholding responsibility under chapters 3 and 4 of the Code and primary Form 1099 reporting and backup withholding responsibility under chapter 61 and section 3406 with respect to a payment, a qualified intermediary shall provide as part of its withholding statement the chapter 3 withholding rate pool information that is required for the withholding agent to meet its withholding and reporting obligations under chapters 3 and 61 of the Code and section 3406. See, however, paragraph (e)(5)(v)(C)(*2*) of this section for when a qualified intermediary may provide a chapter 4 withholding rate pool (as described in paragraph (c)(48) of this section) with respect to a payment that is a withholdable payment. A chapter 3 withholding rate pool is a payment of a single type of income, determined in accordance with the categories of income reported on Form 1042–S, that is subject to a single rate of withholding paid to a payee that is a foreign person and for which withholding under chapter 4 does not apply. A chapter 3 withholding rate pool may be established by any reasonable method on which the qualified intermediary and a withholding agent agree (*e.g.,* by establishing a separate account for a single chapter 3 withholding rate pool, or by dividing a payment made to a single account into portions allocable to each chapter 3 withholding rate pool). A qualified intermediary may include a separate pool for account holders that are U.S. exempt recipients or may include such accounts in a chapter 3 withholding rate pool to which withholding does not apply. The withholding statement must identify the chapter 4 exemption code (as provided in the instructions to Form 1042–S) applicable to the chapter 3 withholding rate pools contained on the withholding statement. To the extent a qualified intermediary does not assume primary Form 1099 reporting and backup withholding responsibility under chapter 61 and section 3406, a qualified intermediary's withholding statement must establish a separate withholding rate pool for each U.S. non-exempt recipient account holder that the qualified intermediary has disclosed to the withholding agent unless the qualified intermediary uses the alternative procedures in paragraph (e)(5)(v)(C)(*3*) of this section or the account holder is a payee that the qualified intermediary is permitted to include in a chapter 4 withholding rate pool of U.S. payees. A qualified intermediary that is a participating FFI or registered deemed- compliant FFI

may include a chapter 4 withholding rate pool of U.S. payees on a withholding statement by applying the rules under paragraph (e)(3)(iv)(A) of this section (by substituting ''qualified intermediary'' for ''nonqualified intermediary'') with respect to an account that it maintains (as described in § 1.1471–5(b)(5)) for the payee of the payment. A qualified intermediary shall determine withholding rate pools based on valid documentation that it obtains under its withholding agreement with the IRS, or if a payment cannot be reliably associated with valid documentation, under the applicable presumption rules. If a qualified intermediary has an account holder that is another intermediary (whether a qualified intermediary or a nonqualified intermediary) or a flow- through entity, the qualified intermediary may combine the account holder information provided by the other intermediary or flow-through entity with the qualified intermediary's direct account holder information to determine the qualified intermediary's chapter 3 withholding rate pools and each of the qualified intermediary's chapter 4 withholding rate pools to the extent provided in its withholding agreement with the IRS.

(*2*) *Withholding rate pool requirements for a withholdable payment.* This paragraph (e)(5)(v)(C)(*2*) modifies the requirements of a withholding statement described in paragraph (e)(5)(v)(C)(*1*) of this section provided by a qualified intermediary with respect to a withholdable payment (including a reportable amount that is a withholdable payment). For such a payment, the regulations applicable to a withholding statement described in paragraph (e)(5)(v)(C)(*1*) of this section shall apply, except that—

(*i*) If the qualified intermediary provides a withholding statement described in § 1.1471–3(c)(3)(iii)(B)(*2*) (describing an FFI withholding statement), the withholding statement may include a chapter 4 withholding rate pool with respect to the portion of the payment allocated to a single pool of recalcitrant account holders (without the need to subdivide into the pools described in § 1.1471–4(d)(6)), including both account holders of the qualified intermediary and of any participating FFI, registered deemed-compliant FFI, or other qualified intermediary for whom the first-mentioned qualified intermediary receives the payment, and nonparticipating FFIs (to the extent permitted) in lieu of reporting chapter 3 withholding rate pools with respect to such persons as described in paragraph (e)(5)(v)(C)(*1*) of this section); or

(*ii*) If the qualified intermediary provides a withholding statement described in § 1.1471–3(c)(3)(iii)(B)(*3*) (describing a chapter 4 withholding statement), the withholding statement may include a chapter 4 withholding rate pool with respect to the portion of the payment allocated to nonparticipating FFIs.

(*3*) *Alternative procedure for U.S. non-exempt recipients.* If permitted under its withholding agreement with the IRS, a qualified intermediary may, by mutual agreement with a withholding agent, establish a single zero withholding rate pool that includes U.S. non-exempt recipient account holders for whom the qualified intermediary has provided Forms W–9 prior to the withholding agent paying any reportable payments, as defined in the qualified intermediary withholding agreement, and foreign persons for which no withholding is required under chapters 3 and 4, and may include payments allocated to a chapter 4 withholding rate pool of U.S. payees. In such a case, the qualified intermediary may also establish a separate withholding rate pool (subject to 28-percent withholding, or other applicable statutory back-up withholding tax rate) that includes only U.S. non-exempt recipient account holders for whom a qualified intermediary has not provided Forms W–9 prior to the withholding agent paying any reportable payments. If a qualified intermediary chooses the alternative procedure of this paragraph (e)(5)(v)(C)(*3*), the qualified intermediary must provide the information required by its withholding agreement to the withholding agent no later than January 15 of the year following the year in which the payments are paid. Failure to provide such information will result in the application of penalties to the qualified intermediary under sections 6721 and 6722, as well as any other applicable penalties, and may result in the termination of the qualified intermediary's withholding agreement with the IRS. A withholding agent shall not be liable for tax, interest, or penalties for failure to backup withhold or report information under chapter 61 of the Code due solely to the errors or omissions of the qualified intermediary. If a qualified intermediary fails to provide the allocation information required by this paragraph (e)(5)(v)(C)(*3*), with respect to U.S. non-exempt recipients, the withholding agent shall report the unallocated amount paid from the withholding rate pool to an unknown recipient, or otherwise in accordance with the appropriate Form 1099 and the instructions accompanying the form.

(*D*) *Example.* The following example illustrates the application of paragraph (e)(5)(v)(C) of this section for a qualified intermediary providing chapter 4 withholding rate pools on an FFI withholding statement provided to a withholding agent. WA makes a payment of U.S. source interest that is a withholdable payment to QI, a qualified intermediary that is an FFI and a non-U.S. payor (as defined in § 1.6049–5(c)(5)), and A and B are account holders of QI (as defined under § 1.1471–5(a)) and are both U.S. non-exempt recipients (as defined in paragraph (c)(21) of this section). Ten percent of the payment is attributable to both A and B. A has provided WA with a Form W–9, but B has not provided WA with a Form W–9. QI assumes primary withholding responsibility under chapters 3 and 4 with respect to the payment, 80 percent of which is allocable to foreign payees who are account holders other than A and B. As a participating FFI, QI is required to report with respect to its U.S. accounts under § 1.1471–4(d) (as incorporated into its qualified intermediary agreement). Provided that QI reports A's account as a U.S. account under the requirements referenced in the preceding sentence, QI is not required to provide WA with a Form W–9 from A and may instead include A in a chapter 4 withholding rate pool of U.S. payees, allocating 10% of the payment to this pool. See § 1.6049–4(c)(4)(iii) concerning when reporting under section 6049 for a payment of interest is not required when an FFI that is a non-U.S. payor reports an account holder receiving the payment under its chapter 4 requirements. With respect to B, the interest payment is subject to backup withholding under section 3406. Because B is a recalcitrant account holder of QI for withholdable payments and because QI assumes primary chapter 4 withholding responsibility, however, QI may include the portion of the payment allocated to B with the remaining 80% of the payment for which QI assumes primary withholding responsibility. WA can reliably associate the full amount of the payment based on the withholding statement and does so regardless of whether WA knows B is a U.S. non-exempt recipient that is receiving a portion of the payment. See § 31.3406(g)–1(e) (providing exemption to backup withholding when withholding was applied under chapter 4).

* * * * *

(f) *Effective/applicability date*—(1) *In general.* Except as otherwise provided in paragraphs (e)(4)(ix)(D), (f)(2), and (f)(3) of this section, this section applies to payments made on or after January 6, 2017. (For payments made after June 30, 2014 (except for payments to which paragraph (e)(4)(ix)(D) applies, in which case, substitute March 5, 2014, for June 30, 2014), and before January 6, 2017, see this section as in effect and contained in 26 CFR part 1, as revised April 1, 2016. For payments made after

December 31, 2000, and before July 1, 2014, see this section as in effect and contained in 26 CFR part 1, as revised April 1, 2013.)

(2) *Lack of documentation for past years.* A taxpayer may elect to apply the provisions of paragraphs (b)(7)(i)(B), (ii), and (iii) of this section, dealing with liability for failure to obtain documentation timely, to all of its open tax years, including tax years that are currently under examination by the IRS. The election is made by simply taking action under those provisions in the same manner as the taxpayer would take action for payments made after December 31, 2000.

(3) *Section 871(m) transactions.* Paragraphs (b)(4)(xxi), (b)(4)(xxiii), (e)(3)(ii)(E), and (e)(6) of this section apply to payments made on or after September 18, 2015.

(4) [Reserved]. For further guidance, see § 1.1441–1T(f)(4).

* * * * *

■ **Par. 4.** Section 1.1441–1T is revised to read as follows:

§ 1.1441–1T Requirement for the deduction and withholding of tax on payments to foreign persons (temporary).

(a) through (b)(7)(ii)(A) [Reserved]. For further guidance, see § 1.1441–1(a) through (b)(7)(ii)(A).

(B) *Special rules for establishing that income is effectively connected with the conduct of a U.S. trade or business.* A withholding certificate received after the date of payment to claim under § 1.1441–4(a)(1) that income is effectively connected with the conduct of a U.S. trade or business will be considered effective as of the date of the payment if the certificate contains a signed affidavit (either at the bottom of the form or on an attached page) that states that the information and representations contained on the certificate were accurate as of the time of the payment. The signed affidavit must also state that the beneficial owner has included the income on its U.S. income tax return for the taxable year in which it is required to report the income or, alternatively, that the beneficial owner intends to include the income on a U.S. income tax return for the taxable year in which it is required to report the income and the due date for filing such return (including any applicable extensions) is after the date on which the affidavit is signed. A certificate received within 30 days after the date of the payment will not be considered to be unreliable solely because it does not contain the affidavit described in the preceding sentences.

(b)(7)(iii) through (c)(2)(i) [Reserved]. For further guidance, see § 1.1441–1(b)(7)(iii) through (c)(2)(i).

(ii) *Dual residents.* Individuals will not be treated as U.S. persons for purposes of this section for a taxable year or any portion of a taxable year for which they are a dual resident taxpayer (within the meaning of § 301.7701(b)–7(a)(1) of this chapter) who is treated as a nonresident alien pursuant to § 301.7701(b)–7(a)(1) of this chapter for purposes of computing their U.S. tax liability.

(c)(3) through (c)(3)(i) [Reserved]. For further guidance, see § 1.1441–1(c)(3) through (c)(3)(i).

(ii) *Nonresident alien individual.* The term *nonresident alien individual* means persons described in section 7701(b)(1)(B), alien individuals who are treated as nonresident aliens pursuant to § 301.7701(b)–7 of this chapter for purposes of computing their U.S. tax liability, or an alien individual who is a resident of Puerto Rico, Guam, the Commonwealth of Northern Mariana Islands, the U.S. Virgin Islands, or American Samoa as determined under § 301.7701(b)–1(d) of this chapter. An alien individual who has made an election under section 6013(g) or (h) to be treated as a resident of the United States is nevertheless treated as a nonresident alien individual for purposes of withholding under chapter 3 of the Code and the regulations thereunder.

(c)(4) through (c)(38)(i) [Reserved]. For further guidance, see § 1.1441–1(c)(4) through (c)(38)(i).

(ii) *Hold mail instruction.* Notwithstanding the provisions of paragraph (i) of this section, an address that is subject to a hold mail instruction can be used as a permanent residence address if the person has also provided the withholding agent with documentary evidence establishing residence in the country in which the person claims to be a resident for tax purposes. If, after a withholding certificate is provided, a person's permanent residence address is subsequently subject to a hold mail instruction, this is a change in circumstances requiring the person to provide the documentary evidence described in this paragraph (c)(38)(ii) in order to use the address as a permanent residence address.

(c)(39) through (e)(2)(ii)(A) [Reserved]. For further guidance, see § 1.1441–1(c)(39) through (e)(2)(ii)(A).

(B) *Requirement to collect foreign TIN and date of birth beginning January 1, 2017.* Beginning January 1, 2017, a beneficial owner withholding certificate provided to document an account that is maintained at a U.S. branch or office of a financial institution is required to contain the account holder's foreign TIN and, in the case of an individual account holder, the account holder's date of birth in order for the withholding agent to treat such withholding certificate as valid under paragraph (e)(2) of this section. For withholding certificates associated with payments made on or after January 1, 2018, if an account holder does not have a foreign TIN, the account holder is required to provide a reasonable explanation for its absence (*e.g.,* the country of residence does not provide TINs) in order for the withholding certificate not to be considered invalid as a result of the application of this paragraph (e)(2)(ii)(B). A withholding certificate that does not contain the account holder's date of birth will not be considered invalid as a result of the application of this paragraph (e)(2)(ii)(B) if the withholding agent has the account holder's date of birth information in its files.

(e)(3) through (e)(3)(iv)(C)(*2*) [Reserved]. For further guidance, see § 1.1441–1(e)(3) through (e)(3)(iv)(C)(*2*).

(*3*) *Alternative withholding statement.* In lieu of a withholding statement containing all of the information described in paragraph (e)(3)(iv)(C)(*1*) of this section, a withholding agent may accept from a nonqualified intermediary a withholding statement that meets all of the requirements of this paragraph (e)(3)(iv)(C)(*3*) with respect to a payment. This alternative withholding statement may only be provided by a nonqualified intermediary that provides the withholding agent with the withholding certificates from the beneficial owners (*i.e.,* not documentary evidence) before the payment is made.

(*i*) The withholding statement is not required to contain information that is also included on a withholding certificate (*e.g.,* name, address, TIN (if any), chapter 4 status, GIIN (if any)). The withholding statement is also not required to specify the rate of withholding to which each foreign payee is subject, provided that all of the information necessary to make such determination is provided on the withholding certificate. A withholding agent that uses an alternative withholding statement may not apply a different rate from that which the withholding agent may reasonably conclude from the information on the withholding certificate.

(*ii*) The withholding statement must allocate the payment to every payee required to be reported as described in paragraph (e)(3)(iv)(C)(*1*)(*ii*) of this section.

(*iii*) The withholding statement must also contain any other information the withholding agent reasonably requests in order to fulfill its obligations under chapters 3, 4, and 61 of the Code, and section 3406.

(*iv*) The withholding statement must contain a representation from the nonqualified intermediary that the information on the withholding certificates is not inconsistent with any other account information the nonqualified intermediary has for the beneficial owners for determining the rate of withholding with respect to each payee.

(e)(3)(iv)(C)(*4*) through (e)(4)(i)(A) [Reserved]. For further guidance, see § 1.1441–1(e)(3)(iv)(C)(*4*) through (e)(4)(i)(A).

(B) *Electronic signatures.* A withholding agent, regardless of whether the withholding agent has established an electronic system pursuant to paragraph (e)(4)(iv)(A) or (e)(4)(iv)(C) of this section, may accept a withholding certificate (other than a Form W–9) with an electronic signature, provided the electronic signature meets the requirements of paragraph (e)(4)(iv)(B)(*3*)(*ii*) of this section. In addition, the withholding certificate must reasonably demonstrate to the withholding agent that the form has been electronically signed by the recipient identified on the form (or a person authorized to sign for the person identified on the form). For example, a withholding agent may treat as validly signed a withholding certificate that has, in the signature block, the name of the person authorized to sign, a time and date stamp, and a statement that the certificate has been electronically signed. However, a withholding agent may not treat a withholding certificate with a typed name in the signature line and no other information as validly signed.

(e)(4)(ii) through (e)(4)(ii)(A)(*1*) [Reserved]. For further guidance, see § 1.1441–1(e)(4)(ii) through (e)(4)(ii)(A)(*1*).

(*2*) *Documentary evidence for treaty claims and treaty statements.* Documentary evidence described in § 1.1441–6(c)(3) or (4) and a statement regarding entitlement to treaty benefits described in § 1.1441–6(c)(5)(i) (treaty statement) shall remain valid until the last day of the third calendar year following the year in which the documentary evidence is provided to the withholding agent except as provided in paragraph (e)(4)(ii)(B) of this section. Notwithstanding the validity period prescribed in this paragraph (e)(4)(ii)(A)(*2*), a treaty statement will cease to be valid if a change in circumstances makes the information on the statement unreliable or incorrect. For accounts opened and treaty statements obtained prior to January 6, 2017, the treaty statement will expire January 1, 2019.

(e)(4)(ii)(B) through (e)(4)(iv)(B)(*4*) [Reserved]. For further guidance, see § 1.1441–1(e)(4)(ii)(B) through (e)(4)(iv)(B)(*4*).

(C) *Form 8233.* A withholding agent may establish a system for a beneficial owner or payee to provide Form 8233 electronically, provided the system meets the requirements of paragraph (e)(4)(iv)(B)(1) through (4) of this section (replacing ''Form W–8'' with ''Form 8233'' each place it appears).

(D) [Reserved]. For further guidance, see § 1.1441–1(e)(4)(iv)(D).

(E) *Third party repositories.* A withholding certificate (other than a Form W–9) will be considered furnished for purposes of this section (including paragraph (e)(1)(ii)(A)(*1*) of this section) by the person providing the certificate, and a withholding agent may rely on an otherwise valid withholding certificate received electronically from a third party repository, if the withholding certificate was uploaded or provided to a third party repository and there are processes in place to ensure that the withholding certificate can be reliably associated with a specific request from the withholding agent and a specific authorization from the person providing the certificate (or an agent of the person providing the certificate) for the withholding agent making the request to receive the withholding certificate. Each request and authorization must be associated with a specific payment, and, as applicable, a specific obligation maintained by a withholding agent. A third party repository may also be used for withholding statements, and a withholding agent may also rely on an otherwise valid withholding statement, if the intermediary providing the withholding certificates and withholding statement through the repository provides an updated withholding statement in the event of any change in the information previously provided (*e.g.,* a change in the composition of a partnership or a change in the allocation of payments to the partners) and ensures there are processes in place to update withholding agents when there is a new withholding statement (and withholding certificates, as necessary) in the event of any change that would affect the validity of the prior withholding certificates or withholding statement. A third party repository, for purposes of this paragraph, is an entity that maintains withholding certificates (including certificates accompanied by withholding statements) but is not an agent of the applicable withholding agent or the person providing the certificate. The following examples illustrate the provisions of this paragraph (e)(4)(iv)(E):

Example 1. A, a foreign corporation, completes a Form W–8BEN–E and a Form W–8ECI and uploads the forms to X, a third party repository (X is an entity that maintains withholding certificates on an electronic data aggregation site). WA, a withholding agent, enters into a contract with A under which it will make payments to A of U.S. source FDAP that are not effectively connected with A's conduct of a trade or business in the United States. X is not an agent of WA or A. Prior to receiving a payment, A sends WA an email with a link that authorizes WA to access A's Form W–8BEN–E on X's system. The link does not authorize WA to access A's Form W–8ECI. X's system meets the requirements of a third party repository, and WA can treat the Form W–8BEN–E as furnished by A.

Example 2. The facts are the same as *Example 1* of this paragraph (e)(4)(iv)(E), and WA and A enter into a second contract under which WA will make payments to A that are effectively connected with A's conduct of a trade or business in the United States. A sends WA an email with a link that gives WA access to A's Form W–8ECI on X's system. The link in this second email does not give WA access to A's Form W–8BEN–E. A's email also clearly indicates that the link is associated with payments received under the second contract. X's system meets the requirements of a third party repository, and WA can treat the Form W–8ECI as furnished by A.

Example 3. FP is a foreign partnership that is acting on behalf of its partners, A and B, who are both foreign individuals. FP completes a Form W–8IMY and uploads it to X, a third party repository. FP also uploads Forms W–8BEN from both A and B and a valid withholding statement allocating 50% of the payment to A and 50% to B. WA is a withholding agent that makes payments to FP as an intermediary for A and B. FP sends WA an email with a link to its Form W–8IMY on X's system. The link also provides WA access to FP's withholding statement and A's and B's Forms W–8BEN. FP also has processes in place that ensure it will provide a new withholding statement or withholding certificate to X's repository in the event of a change in the information previously provided that affects the validity of the withholding statement and that ensure it will update WA if there is a new withholding statement. X's system meets the requirements of a third party repository, and WA can treat the Form W–8IMY (and withholding statement) as furnished by FP. In addition, because FP is acting as an agent of A and B, the beneficial owners, WA can treat the Forms W–8BEN for A and B as furnished by A and B.

(e)(4)(v) through (f)(3) [Reserved]. For further guidance, see § 1.1441–1(e)(4)(v) through (f)(3).

(4) *Effective/applicability date.* This section applies to payments made on or after January 6, 2017.

(g) *Expiration date.* The applicability of this section expires on December 30, 2019.

§ 1.1441–3 [Amended]

■ **Par. 5.** Section 1.1441–3 is amended by removing the second instance of the word ''is'' in the last sentence of paragraph (d)(1).

§ 1.1441–4 [Amended]

■ **Par. 6.** Section 1.1441–4 is amended by removing and reserving paragraph (h).

■ **Par. 7.** Section 1.6045–1 is amended by revising paragraphs (m)(2)(ii) and (n)(12)(ii) to read as follows:

§ 1.6045–1 Returns of information of brokers and barter exchanges.

* * * * *

(m) * * *

(2) * * *

(ii) *Delayed effective date for certain options*—(A) Notwithstanding paragraph (m)(2)(i) of this section, if an option, stock right, or warrant is issued as part of an investment unit described in § 1.1273–2(h), paragraph (m) of this section applies to the option, stock right, or warrant if it is acquired on or after January 1, 2016.

(B) Notwithstanding paragraph (m)(2)(i) of this section, if the property referenced by an option (that is, the property underlying the option) is a debt instrument that is issued by a non-U.S. person or that provides for one or more payments denominated in, or determined by reference to, a currency other than the U.S. dollar, paragraph (m) of this section applies to the option if it is granted or acquired on or after January 1, 2016.

* * * * *

(n) * * *

(12) * * *

(ii) *Effective/applicability date.* Paragraph (n)(12)(i) of this section applies to a debt instrument described in paragraph (n)(12)(i)(A) or (B) of this section that is acquired on or after February 18, 2016. However, a broker may rely on paragraph (n)(12)(i) of this section for a debt instrument described in paragraph (n)(12)(i)(A) or (B) of this section acquired before February 18, 2016.

* * * * *

■ **Par. 8.** Section 1.6049–5 is amended by revising paragraphs (c)(1) through (c)(4) to read as follows:

§ 1.6049–5 Interest and original issue discount subject to reporting after December 31, 1982.

* * * * *

(c) * * *

(1) *Documentary evidence for offshore obligations and certain other obligations*—(i) A payor may rely on documentary evidence described in § 1.1471–3(c)(5)(i) instead of a beneficial owner withholding certificate described in § 1.1441–1(e)(2)(i) in the case of an amount paid outside the United States (as described in paragraph (e) of this section) with respect to an offshore obligation, or, in the case of broker proceeds described in § 1.6045–1(c)(2), to the extent provided in § 1.6045–1(g)(1)(i). For purposes of this section, the term *offshore obligation* means—

(A) An account maintained at an office or branch of a bank or other financial institution located outside the United States; or

(B) An obligation as defined in § 1.6049–4(f)(3) (other than an account described in paragraph (c)(1)(i)(A) of this section), contract, or other instrument with respect to which the payor is either engaged in business as a broker or dealer in securities or a financial institution (as defined in § 1.1471–5(e)) that engages in significant activities at an office or branch located outside the United States. For purposes of the preceding sentence, an office or branch of such payor shall be considered to engage in significant activities with respect to an obligation when it participates materially and actively in negotiating the obligation under the principles described in § 1.864–4(c)(5)(iii) (substituting the term ''obligation'' for the term ''stock or security'').

(ii) A payor may rely on documentary evidence if the payor has established procedures to obtain, review, and maintain documentary evidence sufficient to establish the identity of the payee and the status of that person as a foreign person; and the payor obtains, reviews, and maintains such documentary evidence in accordance with those procedures. A payor maintains the documents reviewed for purposes of this paragraph (c)(1) by retaining an original, certified copy, or photocopy (including a microfiche, electronic scan, or similar means of electronic storage) of the documents reviewed for as long as it may be relevant to the determination of the payor's obligation to report under § 1.6049–4 and this section and noting in its records the date on which the document was received and reviewed. Documentary evidence furnished for a payment of an amount subject to withholding under chapter 3 of the Code or that is a chapter 4 reportable amount under § 1.1474–1(d)(2) must contain all of the information that is necessary to complete a Form 1042–S for that payment. See §§ 1.1471–3(c) and 1.1471–4(c) for additional documentation requirements to identify a payee or account holder for chapter 4 purposes that may apply in addition to the requirements under paragraph (c) of this section.

(iii) Even if an account or obligation (as defined in § 1.6049–4(f)(3)) is not maintained outside the United States (maintained in the United States), a payor may rely on documentary evidence associated with a withholding certificate described in § 1.1441–1(e)(3)(iii) with respect to the persons for whom an entity acting as an intermediary collects the payment. A payor may also rely on documentary evidence associated with a flow-through withholding certificate for payments treated as made to foreign partners of a nonwithholding foreign partnership, as defined in § 1.1441–1(c)(28), the foreign beneficiaries of a foreign simple trust, as defined in § 1.1441–1(c)(24), or foreign owners of a foreign grantor trust, as defined in § 1.1441–1(c)(26), even though the partnership or trust account is an obligation maintained in the United States.

(iv) For accounts opened on or after July 1, 2014, and before January 1, 2015, and for obligations entered into on or after July 1, 2014, and before January 1, 2015, a payor may continue to apply the rules of § 1.6049–5(c)(1) and (c)(4) as in effect and contained in 26 CFR part 1 revised April 1, 2013, rather than this paragraph (c)(1) and paragraph (c)(4) of this section. A payor that applies the rules of § 1.6049–5(c)(1) and (c)(4) as in effect and contained in 26 CFR part 1 revised April 1, 2013, to an account or obligation must also apply § 1.1441–6(c)(2) (to the extent applicable) and § 1.6049–5(e) both as in effect and contained in 26 CFR part 1 revised April, 2013, with respect to the account or obligation.

(2) *Other applicable rules.* The provisions of § 1.1441–1(e)(4)(i) through (xii) (regarding who may sign a certificate, validity period of certificates and documentary evidence, retention of certificates, reliance rules, etc.) shall apply (by substituting the term ''payor'' for the term ''withholding agent'' and disregarding the fact that the provisions under § 1.1441–1(e)(4) only apply to amounts subject to withholding under chapter 3 of the Code) to withholding certificates and documentary evidence furnished for purposes of this section. See § 1.1441–1(b)(2)(vii) for provisions

dealing with reliable association of a payment with documentation.

(3) *Standards of knowledge.* A payor may not rely on a withholding certificate or documentary evidence described in paragraph (c)(1) or (4) of this section if it has actual knowledge or reason to know that any information or certification stated in the certificate or documentary evidence is unreliable. A payor has reason to know that information or certifications are unreliable only if the payor would have reason to know under the provisions of § 1.1441–7(b)(2) and (3) that the information and certifications provided on the certificate or in the documentary evidence are unreliable or, in the case of a Form W–9 (or an acceptable substitute), it cannot reasonably rely on the documentation as set forth in § 31.3406(h)–3(e) of this chapter (see the information and certification described in § 31.3406(h)–3(e)(2)(i) through (iv) of this chapter that are required in order for a payor reasonably to rely on a Form W–9). The provisions of § 1.1441–7(b)(2) and (3) shall apply for purposes of this paragraph (c)(3) irrespective of the type of income to which § 1.1441–7(b)(2) is otherwise limited. The exemptions from reporting described in paragraphs (b)(10) and (11) of this section shall not apply if the payor has actual knowledge that the payee is a U.S. person who is not an exempt recipient.

(4) *Special documentation rules for certain payments.* This paragraph (c)(4) modifies the provisions of paragraph (c)(1) of this section for payments of amounts that are not subject to withholding under chapter 3 of the Code, other than amounts described in paragraph (d)(3)(iii) of this section (dealing with U.S. short-term OID and U.S. source deposit interest described in section 871(i)(2)(A) or 881(d)(3)). Amounts are not subject to withholding under chapter 3 of the Code if they are not included in the definition of amounts subject to withholding under § 1.1441–2(a) (*e.g.,* deposit interest with foreign branches of U.S. banks, foreign source income, or broker proceeds). A payor may rely upon documentation in lieu of documentary evidence (as described in paragraph (c)(1) of this section) or a written statement (as defined in § 1.1471–1(b)(150)) or another statement to the extent permitted in paragraphs (c)(4)(i) through (iii) of this section, until the payor knows or has reason to know of a change in circumstance that makes the documentation unreliable or incorrect (as defined in § 1.1441–1(e)) when the payor does not have customer information for the payee that includes any of the U.S. indicia described in § 1.1471–3(c)(6)(ii)(C)(*1*). Further, a payor may maintain such documentation or documentary evidence as required in paragraph (c)(4)(iv) of this section.

(i) *Statement in lieu of documentary evidence with respect to accounts.* If under the local laws, regulations, or practices of a country in which an account is maintained, it is not customary to obtain documentary evidence described in paragraph (c)(1) of this section with respect to the type of account, the payor may, instead of obtaining a beneficial owner withholding certificate described in § 1.1441–1(e)(2)(i) or documentary evidence described in paragraph (c)(1) of this section, establish a payee's foreign status based on the statement described in this paragraph (c)(4)(i) (or such substitute statement as the Internal Revenue Service may prescribe) made on an account opening form. However, see, also § 1.1471–4(c) or an applicable IGA for additional documentation requirements that may apply to a participating FFI (including a reporting Model 2 FFI) for determining the status of its account holders for chapter 4 purposes. The statement referred to in this paragraph (c)(4)(i) must appear near the signature line and must state, ''By opening this account and signing below, the account owner represents and warrants that he/she/it is not a U.S. person for purposes of U.S. Federal income tax and that he/she/it is not acting for, or on behalf of, a U.S. person. A false statement or misrepresentation of tax status by a U.S. person could lead to penalties under U.S. law. If your tax status changes and you become a U.S. citizen or a resident, you must notify us within 30 days.'' Additionally, a payor may, instead of obtaining a beneficial owner withholding certificate described in § 1.1441–1(e)(2)(i) or § 1.1471–3(c)(3)(ii) or documentary evidence described in paragraph (c)(1) of this section, establish a payee's foreign status based on a written statement described in paragraph § 1.1471–1(b)(150) to the extent a payor uses such written statement to establish a payee's chapter 4 status and is permitted to use the written statement under § 1.1471–3(d) (by substituting the term ''payor'' for the term ''withholding agent'') without any other documentary evidence.

(ii) *Documentation under IGA.* A payor that is a reporting Model 1 FFI or reporting Model 2 FFI may rely upon documentation or information establishing a payee's status that is permitted under an applicable IGA for determining whether the account of the payee is other than a U.S. account and regardless of whether such documentation or certification is described in paragraph (c)(1) of this section or § 1.1441–1(e)(2).

(iii) *Maintenance of documentation and written statement.* A payor maintains documentation if it either maintains the documentary evidence as described in paragraph (c)(1) of this section or retains a record of the documentary evidence reviewed if the payor is not required to retain copies of the documentation pursuant to the payor's AML due diligence (as defined in § 1.1471–1(b)(4)). A payor retains a record of documentary evidence reviewed by noting in its records the type of documentation reviewed, the date the document was reviewed, the document's identification number (if any), and whether such documentation contained any U.S. indicia described in § 1.1441–7(b)(8). Any statement described in paragraph (c)(4)(i) of this section, must be retained in accordance with § 1.1471–3(c)(6)(iii).

* * * * *

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2017–13634 Filed 6–29–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9809]

RIN 1545–BL72

RIN 1545–BN79

Regulations Relating to Information Reporting by Foreign Financial Institutions and Withholding on Certain Payments to Foreign Financial Institutions and Other Foreign Entities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9809) that were published in the **Federal Register** on Friday, January 6, 2017 (82 FR 2124). The final and temporary regulations under chapter 4 of the Subtitle A (sections 1471 through 1474) of the Internal Revenue Code of 1986 (Code) relate to information reporting by foreign financial institutions (FFIs) with respect to U.S. accounts and

withholding on certain payments to FFIs and other foreign entities.

DATES: These corrections are effective June 30, 2017 and are applicable beginning January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Kamela Nelan at (202) 317–6942 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9809) that are the subject of this correction are under sections 1471 through 1474 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9809) contain errors which may prove to be misleading and need to be clarified. Some portions of TD 9809 could not be incorporated due to inaccurate amendatory instructions. Several of the correcting amendments to TD 9809 are needed to clarify or correct the results of inaccurate amendatory instructions. These correcting amendments also include the addition, deletion, or modification of regulatory language to clarify the relevant provisions to meet their intended purposes or for consistency with other related provisions of these regulations. The addition of final regulatory language includes language that was inadvertently removed in a prior amendment to the final regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.1471–1T is amended by revising the third sentence of paragraph (b)(99) to read as follows:

§ 1.1471–1T Scope of chapter 4 and definitions (temporary).

* * * * *

(b) * * *

(99) * * * An address that is provided subject to instructions to hold all mail to that address must be accompanied by certain documentary evidence described in § 1.1441–1(c)(38)(ii). * * *

* * * * *

■ **Par. 3.** Section 1.1471–2 is amended by revising the third sentence of paragraph (a)(2)(i) to read as follows:

§ 1.1471–2 Requirement to deduct and withhold tax on withholdable payments to certain FFIs.

(a) * * *

(2) * * *

(i) * * * Further, a withholding agent is not required to withhold on a payment that it can reliably associate with documentation indicating that the payee is a U.S. branch treated as a U.S. person (as defined in § 1.1471–1(b)(135)) or is a U.S. branch of an FFI that is not treated as a U.S. person but that applies the rules described in § 1.1471–4(d)(2)(iii)(C). * * *

* * * * *

■ **Par. 4.** Section 1.1471–3 is amended by revising paragraph (b)(3) to read as follows:

§ 1.1471–3 Identification of payee.

* * * * *

(b) * * *

(3) *Determination of whether the payment is made to a QI, WP, or WT.* A withholding agent may treat the person who receives a payment as a QI, WP, or WT if the withholding agent can reliably associate the payment with a valid Form W–8IMY, as described in paragraph (c)(3)(iii) of this section, that indicates that the person who receives the payment is a QI, WP, or WT, provides the person's QI–EIN, WP–EIN, or WT–EIN, and the person's GIIN, if applicable.

* * * * *

■ **Par. 5.** Section 1.1471–4 is amended by revising paragraph (d)(3)(ii)(E) and adding a heading to paragraph (d)(7) to read as follows:

§ 1.1471–4 FFI agreement.

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(E) Such other information as is otherwise required to be reported under this paragraph (d)(3) or in the form described in paragraph (d)(3)(v) of this section and its accompanying instructions.

* * * * *

(7) *Special reporting rules with respect to the 2014 and 2015 calendar years—*

* * * * *

■ **Par. 6.** Section 1.1471–4T is amended by revising paragraph (d)(2)(ii)(G) introductory text to read as follows:

§ 1.1471–4T FFI agreement (temporary).

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(G) *Combined reporting on Form 8966 following merger or bulk acquisition.* If a participating FFI (successor) acquires accounts of another participating FFI (predecessor) in a merger or bulk acquisition of accounts, the successor may assume the predecessor's obligations to report the acquired accounts under paragraph (d) of this section with respect the calendar year in which the merger or acquisition occurs (acquisition year), provided that the requirements in paragraphs (d)(2)(ii)(G)(*1*) through (*4*) of this section are satisfied. If the requirements of paragraphs (d)(2)(ii)(G)(*1*) through (*4*) of this section are not satisfied, both the predecessor and the successor are required to report the acquired accounts for the portion of the acquisition year that it maintains the account.

* * * * *

■ **Par. 7.** Section 1.1471–5 is amended by adding paragraph (f)(1)(i)(F)(*3*)(*viii*) and revising paragraph (f)(2)(iii)(C) to read as follows:

§ 1.1471–5 Definitions applicable to section 1471.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(F) * * *

(*3*) * * *

(*viii*) Has not had its status as a sponsoring entity revoked.

* * * * *

(2) * * *

(iii) * * *

(C) Twenty or fewer individuals own all of the debt and equity interests in the FFI (disregarding debt interests owned by U.S. financial institutions, participating FFIs, registered deemed-compliant FFIs, and certified deemed-compliant FFIs and equity interests owned by an entity if that entity owns 100 percent of the equity interests in the FFI and is itself a sponsored FFI under this paragraph (f)(2)(iii)).

* * * * *

■ **Par. 8.** Section 1.1474–1 is amended by:

■ 1. Revising paragraphs (d)(4)(i)(C)(*2*) and (*3*).

■ 2. Adding paragraph (d)(4)(ii)(C).

■ 3. Revising the heading of paragraph (d)(4)(iii), and paragraphs (d)(4)(iii)(A) and (B).

The revisions and addition read as follows:

§ 1.1474–1 Liability for withheld tax and withholding agent reporting.

* * * * *

(d) * * *
(4) * * *
(i) * * *
(C) * * *

(*2*) If the U.S. branch of an FFI is not treated as a U.S. person and applies the rules described in § 1.1471–4(d)(2)(iii)(C) and provides the withholding agent with a withholding certificate that transmits information regarding its reporting pools referenced in paragraph (d)(4)(i)(B) of this section or information regarding each recipient that is an account holder or payee of the U.S. branch, the withholding agent must complete a separate Form 1042–S issued to the U.S. branch for each such pool to the extent required on the form and its accompanying instructions or must complete a separate Form 1042–S issued to each recipient whose documentation is associated with the U.S. branch's withholding certificate as described in paragraph (d)(4)(ii)(A) of this section and report the U.S. branch as an entity not treated as a recipient; or

(*3*) If the U.S. branch of an FFI is not treated as a U.S. person and applies the rules described in § 1.1471–4(d)(2)(iii)(C) to the extent it fails to provide sufficient information regarding its account holders or payees, the withholding agent shall report the recipient of the payment as an unknown recipient to the extent recipient information is not provided and report the U.S. branch as provided in paragraph (d)(4)(ii)(A) of this section for an entity not treated as a recipient.

* * * * *

(ii) * * *

(C) *Disregarded entities.* If a U.S. withholding agent makes a payment to a disregarded entity and receives a valid withholding certificate or other documentary evidence from the person that is the single owner of such disregarded entity, the withholding agent must file a Form 1042–S treating the single owner as the recipient in accordance with the instructions to the Form 1042–S.

(iii) *Reporting by participating FFIs and deemed-compliant FFIs (including QIs, WPs, and WTs) and U.S. branches of FFIs not treated as U.S. persons*—(A) *In general.* Except as otherwise provided in paragraph (d)(4)(iii)(B) (relating to NQIs, NWPs, NWTs, and FFIs electing under section 1471(b)(3)) and § 1.1471–4(d)(2)(ii)(F) (relating to transitional payee-specific reporting for payments to nonparticipating FFIs), a participating FFI or deemed-compliant FFI (including a QI, WP, or WT), and a U.S. branch of an FFI that is not treated as a U.S. person that applies the rules described in § 1.1471–4(d)(2)(iii)(C) that makes a payment that is a chapter 4 reportable amount to a recalcitrant account holder or nonparticipating FFI must complete a Form 1042–S to report such payments. A participating FFI or registered deemed-compliant FFI (including a QI, WP, or WT), and a U.S. branch of an FFI that is not treated as a U.S. person that applies the rules described in § 1.1471–4(d)(2)(iii)(C) may report in pools consisting of its recalcitrant account holders and payees that are nonparticipating FFIs. With respect to recalcitrant account holders, the FFI may report in pools consisting of recalcitrant account holders within a particular status described in § 1.1471–4(d)(6) and within a particular income code. Except as otherwise provided in § 1.1471–4(d)(2)(ii)(F), with respect to payees that are nonparticipating FFIs, the FFI may report in pools consisting of one or more nonparticipating FFIs that fall within a particular income code and within a particular status code described in the instructions to Form 1042–S. Alternatively, a participating FFI or registered deemed-compliant FFI (including a QI, WP, or WT) and a U.S. branch of an FFI that is not treated as a U.S. person that applies the rules described in § 1.1471–4(d)(2)(iii)(C) may (and a certified deemed-compliant FFI is required to) perform payee-specific reporting to report a chapter 4 reportable amount paid to a recalcitrant account holder or a nonparticipating FFI when withholding was applied (or should have applied) to the payment.

(B) *Special reporting requirements of participating FFIs, deemed-compliant FFIs, FFIs that make an election under section 1471(b)(3), and U.S. branches of FFIs not treated as U.S. persons.* Except as otherwise provided in § 1.1471–4(d)(2)(ii)(F), a participating FFI or deemed-compliant FFI that is an NQI, NWP, or NWT, and a U.S. branch of an FFI that is not treated as a U.S. person that applies the rules described in § 1.1471–4(d)(2)(iii)(C) or an FFI that has made an election under section 1471(b)(3) and has provided sufficient information to its withholding agent to withhold and report the payment is not required to report the payment on Form 1042–S as described in paragraph (d)(4)(iii)(A) of this section if the payment is made to a nonparticipating FFI or recalcitrant account holder and its withholding agent has withheld the correct amount of tax on such payment and correctly reported the payment on a Form 1042–S. Such FFI or branch is required to report a payment, however, when the FFI knows, or has reason to know, that less than the required amount has been withheld by the withholding agent on the payment or the withholding agent has not correctly reported the payment on Form 1042–S. In such case, the FFI or branch must report on Form 1042–S to the extent required under paragraph (d)(4)(iii)(A) of this section. See, however, § 1.1471–4(d)(6) for the requirement to report certain aggregate information regarding accounts held by recalcitrant account holders on Form 8966, ''FATCA Report,'' regardless of whether withholdable payments are made to such accounts.

* * * * *

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2017–13632 Filed 6–29–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9819]

RIN 1545–BM06

Guidelines for the Streamlined Process of Applying for Recognition of Section 501(c)(3) Status

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that allow the Commissioner of Internal Revenue to adopt a streamlined application process that eligible organizations may use to apply for recognition of tax-exempt status under section 501(c)(3) of the Internal Revenue Code (Code). The final regulations affect organizations seeking recognition of tax-exempt status under section 501(c)(3).

DATES:

Effective Date: These regulations are effective on June 30, 2017.

Applicability Dates: For dates of applicability, see §§ 1.501(a)–1(f), 1.501(c)(3)–1(h), and 1.508–1(c).

FOR FURTHER INFORMATION CONTACT: Peter A. Holiat at (202) 317–5800 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Since 1969, section 508 of the Code has required an organization seeking tax-exempt status under section 501(c)(3), as a condition of its

exemption, to notify the Secretary of the Treasury (or his delegate) that it is applying for recognition of exempt status in the manner prescribed in regulations, unless it is specifically excepted from the requirement. Longstanding regulations under §§ 1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 had required all organizations applying for recognition of section 501(c)(3) exempt status to submit a properly completed and executed Form 1023, ''Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code,'' (see § 1.508–1(a)(2) as contained in 26 CFR part 1, revised April 1, 2014) and to submit with, and as part of, the application, a detailed statement of its proposed activities (see §§ 1.501(a)–1(b)(1)(iii) and 1.501(c)(3)–1(b)(1)(v) as contained in 26 CFR part 1, revised April 1, 2014). Detailed procedures for applying for recognition of exemption are included in annual revenue procedures and in the instructions for Form 1023. *See* § 601.601(d)(2)(i)(*b*).

On July 2, 2014, final and temporary regulations (TD 9674) authorizing the Commissioner to adopt a streamlined application process that eligible organizations may use to apply for recognition of tax-exempt status under section 501(c)(3) were published in the **Federal Register** (79 FR 37630). The final and temporary regulations were effective and applicable on July 1, 2014. The 2014 final regulations removed and reserved certain paragraphs of the longstanding final regulations addressed by corresponding paragraphs of the new temporary regulations. Under the temporary regulations, the IRS instituted the streamlined application process on Form 1023–EZ, ''Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code,'' the detailed procedures for which have been provided in annual revenue procedures, most recently in Rev. Proc. 2017–5, 2017–1 IRB 230, and in the instructions for Form 1023–EZ.

Also on July 2, 2014, a notice of proposed rulemaking (REG–110948–14) cross-referencing the temporary regulations and soliciting public comments and requests for a hearing was published in the **Federal Register** (79 FR 37697). No comments responding to the notice of proposed rulemaking were received, and no public hearing was requested or held. The IRS continues to consider improvements to Form 1023–EZ based on its own experience and informal comments received from the public and other stakeholders on the form, including whether to require applicants to submit a brief statement of actual or proposed activities. Because the proposed regulations contemplate that guidance published in the Internal Revenue Bulletin may prescribe the information required of Form 1023–EZ filers, including regarding their proposed activities, the Department of the Treasury (Treasury Department) and the IRS have concluded that the proposed regulations are sufficiently flexible to allow such a revision to the Form 1023–EZ at a future date, as resources permit. Accordingly, this Treasury decision adopts as final regulations, without substantive change, the proposed regulations set forth in the 2014 notice of proposed rulemaking and removes the corresponding temporary regulations.

Explanation of Provisions

The Treasury Department and the IRS have considered how the process of meeting the notice requirement of section 508 in seeking recognition of tax-exempt status may be made more efficient for certain smaller organizations. The IRS developed Form 1023–EZ to provide a simplified application form that relies more heavily on attestations by the organization that it meets the section 501(c)(3) organizational and operational requirements, which are explained in the accompanying form instructions. The new form was made available for use by eligible small organizations in July 2014, following the issuance of the temporary regulations and a revenue procedure describing the streamlined application process. The streamlined application process generally allows eligible small organizations to receive IRS determinations of tax-exempt status more quickly and allows the IRS to focus resources on more complex exemption applications and on compliance programs. This Treasury decision adopts the 2014 proposed regulations by amending §§ 1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 to authorize the continued use of the IRS' streamlined process by eligible organizations to meet the notice requirements of section 508.

Specifically, this Treasury decision amends §§ 1.501(a)–1 and 1.501(c)(3)–1, as in effect before July 2, 2014, to authorize the Treasury Department and the IRS to modify, by applicable regulations or other guidance published in the Internal Revenue Bulletin, the requirement that an organization applying for section 501(c)(3) tax-exempt status provide a detailed statement of its proposed activities. This document also amends the § 1.501(a)–1 provisions relating to the Commissioner's ability to revoke a determination because of a change in the law or regulations, or for other good cause, to reference the Commissioner's authority to retroactively revoke a determination under section 7805(b). No substantive change is intended by this amendment. This Treasury decision also amends the requirement in § 1.501(a)–1(b)(3) that an organization claiming to be exempted from filing annual returns file a statement supporting its claim with and as a part of its application. As amended, § 1.501(a)–1(b)(3) allows an organization to file the statement either in its application, or in a manner prescribed in guidance published in the Internal Revenue Bulletin. *See* Rev. Proc. 2017–5 for rules for filing this statement on Form 8940, ''Request for Miscellaneous Determinations.''

In addition, this document amends § 1.508–1 to provide that eligible organizations may use Form 1023–EZ to notify the Commissioner of their applications for tax-exempt status under section 501(c)(3). This Treasury decision also amends §§ 1.501(a)–1 and 1.508–1 to state that the office to which applications should be submitted will be published in the Internal Revenue Bulletin or instructions to the Form 1023 or Form 1023–EZ.

Finally, this Treasury decision incorporates minor revisions within the portions of §§ 1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 that are otherwise being amended. In § 1.501(a)–1(a)(2), the reference to ''internal revenue district'' is removed because such reference has been made obsolete by the enactment of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685. References to a district director in §§ 1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 are also modified as appropriate, as those positions no longer exist within the IRS. Similarly, references to obsolete due dates for filing notices described in section 508 and related transition relief provisions that are no longer relevant have been removed from §§ 1.508–1(a)(2)(i) and (b)(2)(iv). In addition, § 1.508–1(b)(2)(v) has been revised to remove a reference to the instructions for Form 4653, which is no longer in use.

Effective/Applicability Dates

The temporary regulations have applied since July 1, 2014, and this Treasury decision adopts the proposed regulations that cross-referenced the text of those temporary regulations without substantive change. Thus, the final regulations apply on and after July 1, 2014.

Statement of Availability of IRS Documents

Rev. Proc. 2017–5 is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. Although this rule may affect a substantial number of eligible small entities that choose to use Form 1023–EZ to apply for recognition of tax-exempt status under section 501(c)(3), the Form 1023–EZ streamlines the application process, thereby reducing the economic impact on these entities. This rule merely permits use of the streamlined form of application available to satisfy the notice requirements under section 508(a). Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f), the temporary and proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business and no comments were received.

Drafting Information

The principal author of these regulations is Peter A. Holiat of the Office of Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.501(a)–1 is amended by revising paragraphs (a)(2), (b)(1), (b)(3), and (f) to read as follows:

§ 1.501(a)–1 Exemption from taxation.

(a) * * *

(2) An organization, other than an employees' trust described in section 401(a), is not exempt from tax merely because it is not organized and operated for profit. In order to establish its exemption, it is necessary that every such organization claiming exemption file an application form as set forth below with the appropriate office as designated by the Commissioner in guidance published in the Internal Revenue Bulletin, forms, or instructions to the applicable forms. Subject only to the Commissioner's inherent power to revoke rulings, including with retroactive effect as permitted under section 7805(b), because of a change in the law or regulations or for other good cause, an organization that has been determined by the Commissioner (or previously by a district director) to be exempt under section 501(a) or the corresponding provision of prior law may rely upon such determination so long as there are no substantial changes in the organization's character, purposes, or methods of operation. An organization that has been determined to be exempt under the provisions of the Internal Revenue Code of 1939 or prior law is not required to secure a new determination of exemption merely because of the enactment of the Internal Revenue Code of 1954 unless affected by substantive changes in law made by such Code.

* * * * *

(b) *Additional proof by particular classes of organizations*—(1) Unless otherwise prescribed by applicable regulations or other guidance published in the Internal Revenue Bulletin, organizations mentioned below shall submit with and as a part of their applications the following information:

(i) Mutual insurance companies shall submit copies of the policies or certificates of membership issued by them.

(ii) In the case of title holding companies described in section 501(c)(2), if the organization for which title is held has not been specifically notified in writing by the Internal Revenue Service that it is held to be exempt under section 501(a), the title holding company shall submit the information indicated herein as necessary for a determination of the status of the organization for which title is held.

(iii) An organization described in section 501(c)(3) shall submit with, and as a part of, an application filed after July 26, 1959, a detailed statement of its proposed activities.

* * * * *

(3) An organization claiming to be specifically exempted by section 6033(a) from filing annual returns shall submit with and as a part of its application (or in such other manner as is prescribed in guidance published in the Internal Revenue Bulletin) a statement of all the facts on which it bases its claim.

* * * * *

(f) *Effective/applicability date.* Paragraphs (a)(2), (b)(1), and (b)(3) of this section apply on and after July 1, 2014.

Section 1.501(a)–1T [Removed].

■ **Par. 3.** Section 1.501(a)–1T is removed.

■ **Par. 4.** Section 1.501(c)(3)–1 is amended by revising paragraphs (b)(1)(v), (b)(6), and (h) to read as follows:

§ 1.501(c)(3)–1 Organizations organized and operated for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or for the prevention of cruelty to children or animals.

* * * * *

(b) * * *

(1) * * *

(v) Unless otherwise prescribed by applicable regulations or other guidance published in the Internal Revenue Bulletin, an organization must, in order to establish its exemption, submit a detailed statement of its proposed activities with and as a part of its application for exemption (see § 1.501(a)–1(b)).

* * * * *

(6) *Applicability of the organizational test.* A determination by the Commissioner that an organization is described in section 501(c)(3) and exempt under section 501(a) will not be granted after July 26, 1959, regardless of when the application is filed, unless such organization meets the organizational test prescribed by this paragraph (b). If, before July 27, 1959, an organization has been determined by the Commissioner or district director to be exempt as an organization described in section 501(c)(3) or in a corresponding provision of prior law and such determination has not been revoked before such date, the fact that such organization does not meet the organizational test prescribed by this paragraph (b) shall not be a basis for revoking such determination. Accordingly, an organization that has been determined to be exempt before July 27, 1959, and which does not seek

a new determination of exemption is not required to amend its articles of organization to conform to the rules of this paragraph (b), but any organization that seeks a determination of exemption after July 26, 1959, must have articles of organization that meet the rules of this paragraph (b). For the rules relating to whether an organization determined to be exempt before July 27, 1959, is organized exclusively for one or more exempt purposes, see 26 CFR (1939) 39.101(6)–1 (Regulations 118) as made applicable to the Code by Treasury Decision 6091, approved August 16, 1954 (19 FR 5167; 1954–2 CB 47).

* * * * *

(h) *Effective/applicability date.* Paragraphs (b)(1)(v) and (b)(6) of this section apply on and after July 1, 2014.

Section 1.501(c)(3)–1T [Removed].

■ **Par. 5.** Section 1.501(c)(3)–1T is removed.

■ **Par. 6.** Section 1.508–1 is amended by revising paragraphs (a)(2)(i), (a)(2)(ii), (b)(2)(iv), (b)(2)(v), and (c) to read as follows:

§ 1.508–1 Notices.

(a) * * *

(2) *Filing of notice*—(i) For purposes of paragraph (a)(1) of this section, except as provided in paragraph (a)(3) of this section, an organization seeking exemption under section 501(c)(3) must file the notice described in section 508(a) within 15 months from the end of the month in which the organization was organized. Such notice is filed by submitting a properly completed and executed Form 1023 (or, if applicable, Form 1023–EZ) exemption application. Notice should be filed with the appropriate office as designated by the Commissioner in guidance published in the Internal Revenue Bulletin, forms, or instructions to the applicable forms. A request for extension of time for the filing of such notice should be submitted to such appropriate office. Such request may be granted if it demonstrates that additional time is required.

(ii) Although the information required by either Form 1023 or Form 1023–EZ must be submitted to satisfy the notice required by this section, the failure to supply, within the required time, all of the information required to complete such form is not alone sufficient to deny exemption from the date of organization to the date such complete information for such form is submitted by the organization. If the information that is submitted within the required time is incomplete, and the organization supplies the necessary additional information requested by the Commissioner within the additional time period allowed, the original notice will be considered timely.

* * * * *

(b) * * *

(2) * * *

(iv) Any organization filing notice under this paragraph (b)(2)(iv) shall file its notice by submitting a properly completed and executed Form 1023 (or, if applicable, Form 1023–EZ) and providing information that it is not a private foundation. The organization shall also submit all information required by the regulations under section 170 or 509 (whichever is applicable) necessary to establish recognition of its classification as an organization described in section 509(a)(1), (2), (3), or (4). The notice required by this paragraph (b)(2)(iv) should be filed with the appropriate office as designated by the Commissioner in guidance published in the Internal Revenue Bulletin, forms, or instructions to the applicable forms.

(v) An extension of time for the filing of a notice under this paragraph (b)(2) may be granted by the office with which the notice is filed upon timely request by the organization, if the organization demonstrates that additional time is required.

* * * * *

(c) *Effective/applicability date.* Paragraphs (a)(2)(i), (a)(2)(ii), (b)(2)(iv), and (b)(2)(v) of this section apply on and after July 1, 2014.

Section 1.508–1T [Removed].

Par. 7. Section 1.508–1T is removed.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: June 9, 2017.

Thomas West,

Tax Legislative Counsel.

[FR Doc. 2017–13866 Filed 6–29–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9809]

RIN 1545–BL72
RIN 1545–BN79

Regulations Relating to Information Reporting by Foreign Financial Institutions and Withholding on Certain Payments to Foreign Financial Institutions and Other Foreign Entities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correction.

SUMMARY: This document contains a correction to final and temporary regulations (TD 9809) that were published in the **Federal Register** on Friday, January 6, 2017 (82 FR 2124). The final and temporary regulations under chapter 4 of Subtitle A (sections 1471 through 1474) of the Internal Revenue Code of 1986 (Code) relate to information reporting by foreign financial institutions (FFIs) with respect to U.S. accounts and withholding on certain payments to FFIs and other foreign entities.

DATES: This correction is effective June 30, 2017 and is applicable beginning January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Kamela Nelan at (202) 317–6942 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9809) that are subject of this correction are under sections 1471 through 1474 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9809) contain an error that proves to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the final and temporary regulations (TD 9809) that are the subject of FR Doc. 2016–31601 are corrected as follows:

■ On page 2192, column 1, under the title heading PART 301—PROCEDURE AND ADMINISTRATION, the first line, the language ''Par. 23. Need Authority'' is corrected to read ''Par. 23. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.''

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2017–13631 Filed 6–29–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 31

[Docket No. OJP (OJJDP) 1737]

RIN 1121–AA83

Juvenile Justice and Delinquency Prevention Act Formula Grant Program

AGENCY: Office of Justice Programs.

ACTION: Final rule; correcting amendments.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention (''OJJDP'') of the Office of Justice Programs (''OJP'') published in the **Federal Register** on January 17, 2017, a partial Final Rule amending the formula grant program (''Formula Grant Program'') regulation. This technical correction corrects inaccurate citations to sections of the Juvenile Justice and Delinquency Prevention Act (the ''Act'') in the partial Final Rule.

DATES: *Effective Date:* This rule is effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Gregory Thompson, Senior Advisor, Office of Juvenile Justice and Delinquency Prevention, at 202–307–5911.

SUPPLEMENTARY INFORMATION:

Background

The OJJDP Formula Grant Program is authorized by the Juvenile Justice and Delinquency Prevention Act (''JJDPA''), which authorizes OJJDP to provide an annual grant to each State to improve its juvenile justice system and to support juvenile delinquency prevention programs. The partial Final Rule that OJJDP published on January 17, and which took effect on March 21, 2017, amends the implementing regulations for the Formula Grant Program found at 28 CFR part 31. In particular, § 31.303(f)(5) amends States' reporting requirements in several aspects. This technical correction simply corrects inaccurate references to sections of the Act cited in the partial Final Rule.

How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866 and Executive Order 13563

This technical correction has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation, and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1, General Principles of Regulation. This technical correction is limited to amending the citations to sections of the Act and, therefore, is not a ''regulation'' or ''rule'' as defined by that Executive Order.

B. Executive Order 13132

This technical correction to the partial Final Rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, ''Federalism,'' OJP has determined that this technical correction does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

C. Executive Order 12988

This technical correction to the partial Final Rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform.''

D. Administrative Procedures Act

This technical correction simply corrects citations to sections of the Act in the partial Final Rule published on January 17, 2017 and, accordingly, OJP finds it unnecessary to publish this technical correction for public notice and comment. *See* 5 U.S.C. 553(b). Similarly, because delaying the effective date of this technical correction would serve no purpose, OJP also finds good cause to make this rule technical correction effective upon publication. *See* 5 U.S.C. 553(d)(3).

E. Regulatory Flexibility Act

OJP, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this technical correction and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it simply makes a technical correction to the partial Final Rule published on January 17, 2017. Further, a Regulatory Flexibility analysis is not required for this technical correction because OJP was not required to publish a general notice of proposed rulemaking for this matter. *See* 5 U.S.C. 604.

F. Small Business Regulatory Enforcement Fairness Act of 1996

This technical correction is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. This technical correction will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

G. Unfunded Mandates Reform Act of 1995

This technical correction was not preceded by a published notice of proposed rulemaking; will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year; will not significantly or uniquely affect small governments; and does not contain significant intergovernmental mandates. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1535.

H. Paperwork Reduction Act of 1995

This technical correction does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

List of Subjects in 28 CFR Part 31

Authority and Issuance.

PART 31—OJJDP GRANT PROGRAMS

■ 1. The authority citation for 28 CFR part 31 continues to read as follows:

Authority: 42 U.S.C. 5611(b); 42 U.S.C. 5631–5633.

Subpart A—Formula Grants

§ 31.303 [Amended]

■ 2. In § 31.303(f)(5), remove the words ''42 U.S.C. 5633(a)(12), (13), and (14)'' and add in their place ''42 U.S.C. 5633(a)(11), (12), and (13)''.

Dated: June 12, 2017.

Alan R. Hanson,

Acting Assistant Attorney General, Office of Justice Programs.

[FR Doc. 2017–12984 Filed 6–29–17; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2017–0169]

RIN 1625–AA08

Special Local Regulation; Washburn Board Across the Bay, Lake Superior; Chequamegon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard will establish a permanent special local regulation on Lake Superior within Chequamegon Bay for the annual Washburn Board Across the Bay racing event. This annual event historically occurs within the last 2 weeks of July and lasts for 1 day. This action is necessary to safeguard the participants and spectators on the water in a portion of Chequamegon Bay between Washburn, WI and Ashland, WI. This regulation would functionally restrict all vessel speeds while within a designated no-wake zone, unless otherwise specifically authorized by the Captain of the Port (COTP) Duluth or a designated representative. The area forming the subject of this permanent special local regulation is described below.

DATES: This rule is effective July 31, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0169 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Lieutenant Junior Grade John Mack, Waterways management, MSU Duluth, Coast Guard; telephone 218–725–3818, email *John.V.Mack@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On March 30, 2017 the Coast Guard published an NPRM in the **Federal Register** (82 FR 15660) entitled ''Special Local Regulation; Washburn Board Across the Bay, Lake Superior; Chequamegon Bay, WI.'' The NPRM proposed to establish a no-wake zone within Chequamegon Bay on an annual basis during the Washburn Board Across the Bay paddle craft event, and invited comments on our proposed regulatory action related to this paddle craft event. The aforementioned NPRM was open for comment for 30 days in which no comments were received.

III. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on March 30, 2017. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. This rule will create a permanent special local regulation in Chequamegon Bay for the annual Washburn Board Across the Bay racing event that historically takes place in the third or fourth week of July. The no-wake zone will be enforced on all vessels entering into 100 yards of either side of an imaginary line beginning in Washburn, WI at position 46°36′52″ N., 090°54′24″ W.; thence southwest to position 46°38′44″ N., 090°54′50″ W.; thence southeast to position 46°37′02″ N., 090°50′20″ W.; and ending southwest at position 46°36′12″ N., 090°51′51″ W. All vessels transiting through the no-wake zone will be required to travel at an appropriate rate of speed that does not create a wake except as may be permitted by the COTP or a designated representative. The precise times and date of enforcement for this special local regulation will be determined annually.

The COTP, Duluth, will use all appropriate means to notify the public when the special local regulation in this rule will be enforced. Such means may include publication in the **Federal Register** a Notice of Enforcement, Broadcast Notice to Mariners, and Local Notice to Mariners. The regulatory text appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

E.O.s 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits including potential economic, environmental, public health and safety effects, distributive impacts, and equity. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs''), directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has not reviewed it.

As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This regulatory action determination is based on the size, location, duration, and time-of-year of the Special Local Regulation. Vessel traffic will be able to safely transit through the no-wake zone which will be 200 yards wide and will impact only a small designated area of Lake Superior in Chequamegon Bay between Washburn, WI and Ashland, WI during a time of year when commercial vessel traffic is normally low. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and

operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit through the no-wake zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule will have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a no-wake zone being enforced for no more than 5 hours along a prescribed route between Washburn & Ashland, Wisconsin. Normally such actions are categorically excluded from further review under paragraph 34(h) of Figure 2–1 of Commandant Instruction M16475.lD. A preliminary Record of Environmental Consideration and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233

■ 2. Add § 100. 169 to read as follows:

§ 100. 169 Special Local Regulation; Washburn Board Across the Bay, Lake Superior; Chequamegon Bay, WI.

(a) *Location.* All waters of Chequamegon Bay within 100 yards of either side of an imaginary line beginning in Washburn, WI at position 46°36′52″ N., 090°54′24″ W.; thence southwest to position 46°38′44″ N., 090°54′50″ W.; thence southeast to position 46°37′02″ N., 090°50′20″ W.; and ending southwest at position 46°36′12″ N., 090°51′51″ W.

(b) *Effective period.* This annual event historically occurs within the third or fourth week of July. The COTP, Duluth, will announce enforcement dates via Notice of Enforcement, Local Notice to Mariners, Broadcast Notice to Mariners, on-scene designated representatives, or other forms of outreach.

(c) *Regulations.* Vessels transiting within the regulated area shall travel at a no-wake speed except as may be permitted by the COTP, Duluth or a designated on-scene representative. Additionally, vessels shall yield right-of-way for event participants and event safety craft and shall follow directions given by event representatives during the event.

Dated: May 26, 2017.

E.E. Williams,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2017–13559 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0470]

Drawbridge Operation Regulation; Swinomish Channel, Whitmarsh, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Northern Santa Fe Railroad Company (BNSF) Railroad Swing Span Drawbridge 12A across Swinomish Channel, mile 8.4,

near Whitmarsh, WA. This deviation is necessary to accommodate replacement of the bridge protective fendering system. The deviation allows the bridge to remain in the closed-to-navigation position at various times based on low tide predictions; and also allows the swing span to not completely open at various times detained herein.

DATES: This deviation is effective from 7 a.m. on July 1, 2017 to 6 p.m. on November 30, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0470] is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: BNSF (bridge owner) has requested the BNSF Railroad Swing Span Drawbridge 12 be allowed to close the span, and need not open to marine traffic to facilitate fender replacements. The BNSF Railroad Swing Span Drawbridge 12A crosses the Swinomish channel, mile 8.4, near Whitmarsh, WA. The swing span provides 8 feet of vertical clearance in the closed-to-navigation position, and 100 feet of horizontal clearance in the open-to-navigation position. The span provides unlimited vertical clearance in the open-to-navigation position. Vertical and horizontal clearances are referenced to mean high-water elevation.

The closures of the BNSF Railroad Swing Span Drawbridge for the fender replacements will depend on the tidal status of the river, which means that work (and closure), will occur on different times on different days. The specific times of the bridge closures will be published in the weekly Coast Guard Local Notice to Mariners. BNSF work requires the swing span to be in the closed-to-navigation position when the ebb tide height reaches plus three feet above Mean Tide Level, and open the span when the flood tide height reaches plus three feet above Mean Tide Level. The deviation period allows the subject bridge to be in the closed-to-navigation position from 6 a.m. on July 1, 2017 to 6 p.m. on November 30, 2017, when the river is a plus three foot ebb tide, and open the bridge span on a plus three foot flood tide Monday through Saturday. However, if the project gets delayed, work on Sundays will be required.

The swing span at various times will only be able to open to 97 percent. This reduces the horizontal navigation clearance by five feet—from 100 feet to 95 feet. The five feet of horizontal clearance is needed to position work barges at various locations to replace fenders.

During the dates and times of the deviation, the drawbridge will not be able to operate according to the normal operating schedule. This drawbridge normally operates in accordance with 33 CFR 117.5. The subject bridge is normally maintained in the open-to-navigation position. The bridge shall operate in accordance to 33 CFR 117.5 at all other times. Waterway usage on the Swinomish Channel includes commercial tugs and barges, U.S. Coast Guard vessels, and large to small pleasure craft. The Coast Guard provided notice of this deviation to local mariners via the Local Notice Mariners and emails. One objection was submitted to the Coast Guard, and requested bridge closure times be posted in the Local Notice to Mariners. As stated herein, specific times will be published in the weekly Local Notice to Mariners.

Vessels will not be able to pass through the swing span via the marked navigation channel during the closure times. Working barges will be positioned in the channel at the bridge during the closed-to-navigation periods preventing safe passage. An alternate route is via the southern Swinomish Channel using Skagit Bay. The bridge will not be able to open for vessels responding to emergencies during the stated closure times. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: June 23, 2017.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2017–13745 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0365]

Drawbridge Operation Regulation; Lewis Creek Channel, Chincoteague, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the SR 175 Bridge that carries the SR 175 across the Lewis Creek Channel, mile 0.0, at Chincoteague, VA. The deviation is necessary to facilitate the Annual Pony Run. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: The deviation is effective from 7 a.m. on Wednesday July 26, 2017, through 5 p.m. on Thursday July 27, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0365] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6557, email *Michael.R.Thorogood@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Virginia Department of Transportation, owner and operator of the SR 175 Bridge that carries the SR 175 Bridge across the Lewis Creek Channel, mile 0.0, at Chincoteague, VA, has requested a temporary deviation from the current operating regulations to ensure the safety of the increased volumes of spectators that will be attending Annual Pony Run on Wednesday July 26, 2017, and Thursday July 27, 2017. This bridge is a bascule span drawbridge with a vertical clearance of 15 feet above mean high water in the closed position and unlimited vertical clearance in the open position. The current operating regulation is set out in 33 CFR 117.5. Under this temporary deviation, the bridge will be maintained in the closed-to-navigation position from 7 a.m. to 5 p.m. on Wednesday July 26, 2017 and Thursday July 27, 2017.

The Lewis Creek Channel is used by recreational vessels. The Coast Guard has carefully considered the nature and volume of vessel traffic on the waterway in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies and there is no immediate alternative route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: June 26, 2017.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2017–13753 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0617]

Safety Zones; Annual Firework Displays Within the Captain of the Port, Puget Sound

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce five safety zones for annual firework displays in the Captain of the Port, Puget Sound Zone during the dates and times noted under **SUPPLEMENTARY INFORMATION.** This action is necessary to prevent injury and to protect life and property of the maritime public from the hazards associated with the firework displays. During the enforcement periods, entry into, transit through, mooring, or anchoring within these safety zones is prohibited unless authorized by the Captain of the Port, Puget Sound or their Designated Representative.

DATES: The regulations in 33 CFR 165.1332 will be enforced for the five safety zones listed under **SUPPLEMENTARY INFORMATION** from 5 p.m. on July 4, 2017, through 1 a.m. on July 5, 2017 during the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Zachary Spence, Sector Puget Sound Waterways Management, Coast Guard; telephone 206–217–6051, *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce regulations for the following five safety zones established for Annual Fireworks Displays within the Captain of the Port, Puget Sound Area of Responsibility in 33 CFR 165.1332 during the dates and times noted in the table below.

The following safety zones will be enforced from 5 p.m. on July 4, 2017, through 1 a.m. on July 5, 2017:

Event name	Location	Latitude	Longitude
Tacoma Freedom Fair	Commencement Bay	47°17.103′ N.	122°28.410′ W.
Friday Harbor Independence	Friday Harbor	48°32.255′ N.	123°0.654.033′ W.
Three Tree Point Community Fireworks	Three Tree Point	47°27.033′ N.	122°23.15′ W.
Everett 4th of July	Port Gardner	48°0.672′ N.	122°13.391′ W.
Seattle Seafair	Lake Washington	47° 34.333′ N.	122° 16.017′ W.

The special requirements listed in 33 CFR 165.1332(b) apply to the activation and enforcement of these safety zones. All vessel operators who desire to enter the safety zone must obtain permission from the Captain of the Port or their Designated Representative by contacting the Coast Guard Sector Puget Sound Joint Harbor Operations Center (JHOC) on VHF Ch 13 or Ch 16 or via telephone at (206) 217–6002.

The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice of enforcement is issued under authority of 33 CFR 165.1332 and 5 U.S.C. 552(a). In addition to the publication of this document in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advanced notification of enforcement of these safety zones via the Local Notice to Mariners and marine information broadcasts on the day of the events.

Dated: June 26, 2017.

L.A. Sturgis,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2017–13682 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0613]

Safety Zone; City of Richmond Fourth of July Fireworks Display, San Francisco Bay, Richmond, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the annual City of Richmond Fourth of July Fireworks Display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 9, will be enforced from 8 a.m. on July 1, 2017 to 10 p.m. on July 3, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a 100 foot safety zone around the fireworks barge during the loading, transit, and arrival of the fireworks barge from the loading location to the display location and until the start of the fireworks display. From 8 a.m. on July 1, 2017 until 5 p.m. on July 3, 2017, the fireworks barge will be loading pyrotechnics from Pier 50 in San Francisco, CA. The fireworks barge will remain at the loading location until its transit to the display location. From 6 p.m. to 8:30 p.m. on July 3, 2017, the loaded fireworks barge will transit from Pier 50 to the launch site in Richmond Marina in approximate position 37°54′40″ N., 122°21′05″ W. (NAD 83) where it will remain until the conclusion of the fireworks display. Upon the commencement of the 20-minute fireworks display, scheduled to begin at 9:30 p.m. on July 3, 2017, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius 560 feet in Richmond Marina in approximate position 37°54′40″ N., 122°21′05″ W. (NAD 83) for the Fourth of July Fireworks, City of Richmond in 33 CFR 165.1191, Table 1, Item number 9. This safety zone will be in effect from 8 a.m. on July 1, 2017 until 10 p.m. on July 3, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so. This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 4, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13841 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0589]

Safety Zone; Delaware River, Philadelphia, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone regulation for an annual fireworks event on the Delaware River, Philadelphia, PA from 9:30 p.m. to 11:30 p.m. on June 30, 2017 and July 1, 2017. Enforcement of this safety zone is necessary and intended to ensure safety of life on navigable waters immediately prior to, during, and immediately after these fireworks events. During the enforcement periods, no vessel may transit this regulated area without approval from the Captain of the Port or a designated representative.

DATES: The regulations in 33 CFR 165.506 will be enforced from 9:30 p.m. to 11:30 p.m. on June 30, 2017 and July 1, 2017, for the safety zone listed in the Table to § 165.506, line (a.)(16).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, you may call or email MST2 Amanda Boone, Sector Delaware Bay Waterways Management Division, U.S. Coast Guard; telephone 215–271–4889, email *Amanda.N.Boone@uscg.mil.*

SUPPLEMENTARY INFORMATION: From 9:30 p.m. to 11:30 p.m. on June 30, 2017 and July 1, 2017, the Coast Guard will enforce the safety zone regulation listed in the Table to 33 CFR 165.506 (a.)(16) that takes place on the Delaware River, Philadelphia, PA. This action is being taken to enhance the safety of life on navigable waterways during the fireworks display.

Coast Guard regulations for recurring firework events in Captain of the Port Delaware Bay Zone, are published in § 165.506, Safety Zones; Fireworks Displays within the Fifth Coast Guard District, which specifies the location of the regulated area for this safety zone as all waters of Delaware River, adjacent to Penns Landing, Philadelphia, PA, bounded from shoreline to shoreline, bounded on the south by a line running east to west from points along the shoreline at latitude 39°56′31.2″ N., longitude 075°08′28.1″ W.; thence west to latitude 39°56′29.1″ N., longitude 075°07′56.5″ W., and bounded on the north where the Benjamin Franklin Bridge crosses the Delaware River.

As specified in § 165.506, during the enforcement period, no vessel or person may enter, transit through, anchor in, or remain within the regulated area unless authorized by the Captain of the Port Delaware Bay or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP, designated representative or Patrol Commander.

This notice of enforcement is issued under authority of 33 CFR 165.506 and 33 U.S.C. 1233. The Coast Guard will provide the maritime community with advanced notice of enforcement of regulation by Broadcast Notice to Mariners (BNM), Local Notice to Mariners and on-scene actual notice by designated representative. In the event Captain of the Port Delaware Bay determines that it's not necessary to enforce the regulated area for the entire duration of the enforcement period, a BNM will be issued to authorize general permission to enter the regulated area.

Dated: Jun 27, 2017.

Scott E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2017–13917 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0539]

Safety Zones; Coast Guard Sector Ohio Valley Annual and Recurring Safety Zones

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce several recurring safety zones on navigable waterways within Sector Ohio Valley. This regulatory action is necessary to provide for the safety of life and protection of vessels from the hazards associated with fireworks displays, festivals, and events. During the enforcement period, entry into these safety zones is prohibited unless

specifically authorized by the Captain of the Port Ohio Valley (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, will be enforced for the safety zones within Sector Ohio Valley as identified in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer James Robinson, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5347, email *James.C.Robinson@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.801, Table 1, lines 13, 17, 19, 21, 22, 23, 24, 25, 26, 27, 29, 50, and 69 as follows:

Line 13, Riverview Park Independence Festival, from 9:30 p.m. through 11 p.m. on July 1, 2017; Line 17, Louisville Bats Firework Show, from 9 p.m. through 11 p.m. on July 4, 2017; Line 19, All American 4th of July, from 9 p.m. through 10 p.m. on July 4, 2017; Line 21, Spirit of Freedom Fireworks, from 9 p.m. through 9:30 p.m. on July 4, 2017; Line 22, Lighting up the Cumberlands Fireworks, from 9 p.m. through 9:30 p.m. on July 1, 2017; Line 23, Knoxville July 4th Fireworks, from 9:40 p.m. through 10:10 p.m. on July 4, 2017; Line 24, Music City July 4th, from 9 p.m. through 9:30 p.m. on July 4, 2017; Line 25, Grand Harbor Marina July 4th Celebration, from 10 p.m. through 10:20 p.m. on July 1, 2017; Line 26, City of Bellevue, KY/Bellevue Beach Park Concert Fireworks, from 9 p.m. through 11 p.m. on July 08, 2017; Line 27, Cincinnati Bell, WEBN, and Proctor Riverfest, from 12 p.m. to 10 p.m. on September 3, 2017; Line 29, City of Point Pleasant/Point Pleasant Sternwheel Fireworks, from 9:30 p.m. through 10 p.m. on July 1, 2017; Line 50, Evansville Freedom Celebration, from 9:45 p.m. through 10:15 p.m. on July 4, 2017; and Line 69, Newburgh Fireworks Display, from 9:45 p.m. through 10:10 p.m. on July 1, 2017. The regulations for the Coast Guard Sector Ohio Valley Annual and Recurring Safety Zones, § 165.801, Table 1, specifies the locations of these safety zones. As specified in § 165.23, during the enforcement period, no vessel may transit these safety zones without approval from the Captain of the Port Ohio Valley (COTP) or a designated representative. Sector Ohio Valley may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

This notice of enforcement is issued under authority of 33 CFR 165.801 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Local Notice to Mariners and updates via Marine Information Broadcasts.

Dated: June 26, 2017.

M.B. Zamperini,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2017–13766 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0606]

Safety Zone; Fourth of July Fireworks, City of Pittsburg, Suisun Bay, Pittsburg, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the City of Pittsburg Fourth of July Fireworks display, in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 13 will be enforced from 9:30 p.m. to 10 p.m. on July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 13 on July 4, 2017. Upon commencement of the 20 minute fireworks display, scheduled to begin at 9:30 p.m. on July 4, 2017, the safety zone will encompass the navigable waters surrounding the land based launch site on the Pittsburg Marina Pier in approximate position 38°02′32″ N., 121°53′19″ W. (NAD 83). Upon the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 9:30 p.m. to 10 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notification in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 4, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13848 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0610]

Safety Zone; Execpro Services Fourth of July Fireworks, Incline Village, NV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the annual Execpro Services Fourth of July Fireworks Display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the

hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 28, will be enforced from 6 a.m. on July 1, 2017 to 10:30 p.m. on July 3, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a 100 foot safety zone around the fireworks barge during the loading, transit, and arrival of the fireworks barge from the loading location to the display location and until the start of the fireworks display. From 6 a.m. on July 1, 2017 until 8 a.m. on July 1, 2017, the fireworks barge will be loading pyrotechnics Obexers Marina in Homewood, CA. The fireworks barge will remain at the loading location until its transit to the display location. From approximately 8 a.m. to 10 a.m. on July 1, 2017, the loaded fireworks barge will transit from Obexers Marina to the launch site off-shore from Incline Village, NV in approximate position 39°13′54″ N., 119°56′25″ W. (NAD 83) where it will remain until the conclusion of the fireworks display. Upon the commencement of the 24-minute fireworks display, scheduled to begin at 9:30 p.m. on July 3, 2017, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet, off-shore from Incline Village, NV, in approximate position 39°13′54″ N., 119°56′25″ W. (NAD 83) for the Execpro Services Fourth of July Fireworks in 33 CFR 165.1191, Table 1, Item number 28. This safety zone will be in effect from 6 a.m. on July 1, 2017 until 10:30 p.m. on July 3, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM.

Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552 (a). In addition to this notification in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 1, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13836 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0310]

RIN 1625–AA00

Safety Zone: Vengeance Sunken Barge, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in support of the environmental and salvage response operation to the sunken barge Vengeance in the San Francisco Bay, east of Yerba Buena Island and north of the Oakland Outer Harbor Entrance Channel near Oakland, CA. All vessel traffic is prohibited from transiting the area to allow safe response operations to be conducted. All vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative.

DATES: This rule is effective without actual notice from June 30, 2017 until July 31, 2017. For the purposes of enforcement, actual notice will be used from June 1, 2017 until June 30, 2017.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2017–0310. To view these documents go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Marcia Medina, U.S. Coast Guard Sector San Francisco; telephone (415) 399–7443 or email at *D11-PF-MarineEvents@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

APA Administrative Procedures Act
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NAD North American Datum of 1983
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.''

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing an NPRM would be impractical due to the emergent nature of the environmental and salvage response to be conducted on the barge Vengeance.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard finds that it is impracticable to provide notice and receive comment due to the emergent nature of the environmental and salvage response to be conducted on the barge Vengeance.

III. Legal Authority and Need for Rule

The legal basis for the proposed rule is 33 U.S.C 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish safety zones.

The sunken barge Vengeance creates a significant underwater hazard to navigation to vessels transiting the San Francisco Bay. The response operations are complex in nature and involve

multiple vessels. These operations, when conducted in close proximity to transiting vessels, create unpredictable hazards, hence necessitating a safety zone restricting all vessel traffic within this impacted area until environmental response operations are complete. This safety zone establishes a temporary restricted area on the navigable waters of the San Francisco Bay, east of Yerba Buena Island and north of Oakland Outer Harbor Entrance Channel within the following points: 37°48.549′ N. 122°20.891′ W., 37°48.498′ N. 122°21.134′ W., 37°48.346′ N. 122°21.068′ W., and 37°48.461′ N. 122°20.782′ W. (NAD 83). This restricted area applies to all vessels transiting the specified area.

IV. Discussion of the Rule

The Coast Guard or a designated representative will enforce a safety zone in navigable waters of the San Francisco Bay, east of Yerba Buena Island and north of Oakland Outer Harbor Entrance Channel within the following points: 37°48.549′ N. 122°20.891′ W., 37°48.498′ N. 122°21.134′ W., 37°48.346′ N. 122°21.068′ W., and 37°48.461′ N. 122°20.782′ W. (NAD 83).

This safety zone is effective from June 1, 2017 through on July 31, 2017 or as announced via Broadcast Notice to Mariners.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the sunken barge Vengeance until the environmental and salvage response operations are complete. Except for persons or vessels authorized by the Captain of the Port or a designated representative, no vessel may enter or remain in the restricted area. These regulations are needed to keep vessels safely outside of the response zone until environmental and salvage response operations are complete.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

E.O.s 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits including potential economic, environmental, public health and safety effects, distributive impacts, and equity. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs''), directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has not reviewed it.

As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

We expect the economic impact of this rule will not rise to the level of necessitating a full Regulatory Evaluation. The safety zone is limited in duration, and is limited to a narrowly tailored geographic area. In addition, although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because it is outside of the Oakland Outer Harbor Entrance Channel and will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

B. Impact on Small Entities

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

This rule may affect the following entities, some of which may be small entities: Owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing, if these facilities or vessels are in the vicinity of the safety zone at times when this zone is being enforced. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This rule will encompass only a small portion of the waterway for a limited period of time, (ii) vessel traffic can transit safely around the safety zone, and (iii) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone of limited size and duration. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration for categorically excluded actions is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–857 to read as follows:

§ 165.T11–857 Safety Zone; Vengeance Sunken Barge, San Francisco, CA.

(a) *Location.* This temporary safety zone is established in the navigable waters of San Francisco Bay, east of Yerba Buena Island and north of Oakland Outer Harbor Entrance Channel within the following points: 37°48.549′ N. 122°20.891′ W., 37°48.498′ N. 122°21.134′ W., 37°48.346′ N. 122°21.068′ W., and 37°48.461′ N. 122°20.782′ W. (NAD 83).

(b) *Enforcement period.* The zone described in paragraph (a) of this section will be enforced from June 1, 2017 through July 31, 2017 or as announced via Broadcast Notice to Mariner. The Captain of the Port San Francisco (COTP) will notify the maritime community of any changes to this enforcement period via Broadcast Notice to Mariners in accordance with 33 CFR 165.7.

(c) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in 33 CFR part 165, subpart C, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zone through the 24-hour Command Center at telephone (415) 399–3547 or on VHF channel 16.

Dated: June 1, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13648 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0825]

RIN 1625–AA00

Safety Zone; United Illuminating Company, Housatonic River Crossing Project; Milford and Stratford, CT

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is amending a temporary safety zone on the Housatonic River near Milford and Stratford, CT. Amending the safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the United Illuminating Company Housatonic River Crossing Project. This regulation prohibits entry of vessels or people into the safety zone unless authorized by the Captain of the Port Sector Long Island Sound. The safety zone will only be enforced during cable pulling operations or other instances which may create a hazard to navigation.

DATES: This rule is effective without actual notice from June 30, 2017 through August 31, 2017. For the purposes of enforcement, actual notice will be used from June 12, 2017 through June 30, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0825 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Katherine Linnick, Prevention Department, U.S. Coast Guard Sector Long Island Sound,

telephone (203) 468–4565, email *Katherine.E.Linnick@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LIS Long Island Sound
NPRM Notice of Proposed Rulemaking
NAD 83 North American Datum 1983
TFR Temporary final rule

II. Background Information and Regulatory History

This rulemaking amends a temporary safety zone for certain waters of the Housatonic River near Milford and Stratford, CT. Corresponding regulatory history is discussed below.

On August 25, 2016, United Illuminating Company notified the Coast Guard that it would conduct a project involving the installation of new transmission conductors over the Housatonic River near Stratford and Milford, CT. On March 14, 2017, the Coast Guard published a NPRM entitled, ''Safety Zone; United Illuminating Company Housatonic River Crossing Project; Housatonic River; Milford and Stratford, CT'' in the **Federal Register** (80 FR 13572). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this transmission project. During the comment period that ended April 13, 2017, we received zero comments.

On May 22, 2017, the Coast Guard published a TFR entitled, ''Safety Zone; United Illuminating Company Housatonic River Crossing Project; Housatonic River; Milford and Stratford, CT'' in the **Federal Register** (82 FR 23144). This project was schedule to be completed in two phases. The first phase involving the stringing of optical fiber ground wires on the North circuit of the project was scheduled to begin on April, 26, 2017 through May 4, 2017. The second phase involves the stringing of optical fiber ground wires on the South circuit from July 29, 2017 through August 3, 2017.

On May 10, 2017, United Illuminating Company notified the Coast Guard that due to foul weather it was behind schedule and was unable to complete phase one as described in the above-mentioned TFR. The project is now scheduled to begin on June 12, 2017 and be completed by August 31, 2017. Due to fluctuations in the project's schedule, the safety zone is being amended to permit enforcement of the safety zone during re-scheduled cable installation operations or other instances which may cause a hazard to navigation. The COTP Long Island Sound (LIS) has determined that the potential hazards associated with the cable installation project could be a safety concern for anyone within the work area. The work area is between the eastern and western shores of the Housatonic River. The southern boundary of the work zone begins at the Metro-North Rail Bridge and extends north approximately 525 feet upstream.

The Coast Guard is amending § 165.T01–0825 without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM with respect to this rule because doing so would be impracticable and contrary to the public interest. The late finalization of project details after weather delays did not give the Coast Guard enough time to publish an NPRM, take public comments regarding the amendments to § 165.T01–0825, and issue a new final rule before the rescheduled cable crossing operation is set to begin. It would be impracticable and contrary to the public interest to delay promulgating the amendments to this rule as it is necessary to protect the safety of the public and waterway users.

Under 5 U.S.C. 553(d)(3), and for the same reasons stated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The legal basis for this temporary rule is 33 U.S.C. 1231. The COTP LIS has determined that potential hazards associated with the river cable crossing project starting on June 12, 2017 and continuing through August 31, 2017 will be a safety concern for anyone within the work zone. This rule is needed to protect people and vessels within the safety zone while the cable crossing project is completed.

IV. Discussion of the Rule

This rule amends the temporary safety zone in § 165.T01–0825. The safety zone will cover all navigable waters of the Housatonic River near Milford and Stratford, CT contained within the following area: Beginning at a point on land in position at 41°12′17″ N., 073°06′40″ W. near the Governor John Davis Lodge Turnpike (I–95) Bridge; then northeast across the Housatonic River to a point on land in position at 41°12′20″ N., 073°06′29″ W. near the Governor John Davis Lodge Turnpike (I–95) Bridge; then northwest along the shoreline to a point on land in position at 41°12′25″ N., 073°06′31″ W.; then southwest across the Housatonic River to a point on land in position at 41°12′22″ N., 073°06′43″ W.; then southeast along the shoreline back to point of origin (NAD 83). All positions are approximate. The duration of the zone is intended to ensure the safety of people and vessels in these navigable waters during any instance that necessitates a temporary closure of the Housatonic River at the work site. The safety zone will only be enforced during cable installation operations or other instances, when they cause a hazard to navigation. During enforcement periods, no vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners via VHF–FM marine channel16 eight hours in advance of any scheduled enforcement period. The regulatory text we are enforcing appears at the end of this document.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone which will affect a small, designated area of the Housatonic River for less than one hour

at a time. It also may be enforced temporarily during the cable installation project if necessitated by an emergency. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit this regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator. Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**.

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

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This temporary rule involves a safety zone enforced for less than one hour at a time that would prohibit entry within the work zone during cable installation. It also may be enforced temporarily during the cable installation project if necessitated by an emergency, such as equipment falling from the towers into the Housatonic River. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. A Record of Environmental Consideration (REC) is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.T01–0825 to read as follows:

§ 165.T01–0825 Safety Zone; United Illuminating Company; Housatonic River Crossing Project; Milford and Stratford, CT.

(a) *Location.* The following area is a safety zone: All navigable waters of the Housatonic River near Milford and Stratford, CT contained within the following area; beginning at a point on land in position at 41°12′17″ N., 073°06′40″ W. near the Governor John Davis Lodge Turnpike (I–95) Bridge; then northeast across the Housatonic River to a point on land in position at 41°12′20″ N., 073°06′29″ W. near the Governor John Davis Lodge Turnpike (I–95) Bridge; then northwest along the shoreline to a point on land in position at 41°12′25″ N., 073°06′31″ W.; then southwest across the Housatonic River to a point on land in position at 41°12′22″ N., 073°06′43″ W.; then southeast along the shoreline back to point of origin (NAD 83). All positions are approximate.

(b) *Effective and enforcement period.* This rule will be effective from 8:00 a.m. on June 12, 2017 to 6:00 p.m. on August 31, 2017, but will only be enforced during cable installation operations or other instances which may cause a hazard to navigation, when deemed necessary by the Captain of the Port (COTP), Sector Long Island Sound. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 eight hours in advance to any scheduled period of enforcement or as soon as practicable in response to an emergency.

(c) *Definitions.* The following definitions apply to this section: A ''designated representative'' is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the COTP, Sector Long Island Sound, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. ''Official patrol vessels'' may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP, Sector Long Island Sound. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation. A ''work vessel'' is any vessel provided by United Illuminating Company for the Housatonic River Crossing Project and may be hailed via VHF channel 13 or 16.

(d) *Regulations.* (1) The general regulations contained in § 165.23 apply.

(2) In accordance with the general regulations in § 165.23, entry into or movement within this zone is prohibited unless authorized by the COTP Long Island Sound.

(3) Operators of vessels desiring to enter or operate within the safety zone should contact the COTP Long Island Sound at 203–468–4401 (Sector Long Island Sound Command Center) or the designated representative via VHF channel 16 to obtain permission to do so. Request to enter or operate in the safety zone must be made 24 hours in advanced of the planned undertaking.

(4) Mariners are requested to proceed with caution after passing arrangements have been made. Mariners are requested to cooperate with the United Illuminating Company work vessels for the safety of all concerned. The United Illuminating Company work vessels will be monitoring VHF channels 13 and 16. Mariners are requested to proceed with extreme caution and operate at their slowest safe speed as to not cause a wake.

(5) Any vessel given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP Long Island Sound, or the designated on-scene representative.

(6) Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

Dated: June 8, 2017.

A.E. Tucci,

Captain, U. S. Coast Guard, Captain of the Port Long Island Sound.

[FR Doc. 2017–13330 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0608]

Safety Zone; Fourth of July Fireworks Display, Tahoe City, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Fourth of July Fireworks Display, Tahoe City, CA in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 15, will be enforced from 7 a.m. to 10:30 p.m. on July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Christina Ramirez, Sector San Francisco Waterways Safety Division, U.S. Coast Guard; telephone 415–399–2001, email *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in navigable waters around and under the fireworks barge within a radius of 100 feet during the loading, transit, and arrival of the fireworks barge to the display location and until the start of the fireworks display. From 7 a.m. until 10 a.m. on July 4, 2017, the fireworks barge will be loading pyrotechnics at the Kings Beach Boat Ramp, in Kings Beach, CA. From approximately 10 a.m. to noon on July 4, 2017, the loaded fireworks barge will transit from the Kings Beach Boat Ramp to the launch site off of Commons Beach in Tahoe City, CA in approximate position 39°10′03″ N., 120°08′09″ W. (NAD 83) where it will remain until the commencement of the fireworks display. Upon the commencement of the 20 minute fireworks display, scheduled to begin at approximately 9:30 p.m. on July 4, 2017, the safety zone will increase in size to encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet in approximate position 39°10′03″ N., 120°08′09″ W. (NAD 83) for the Fourth of July Fireworks, Tahoe City, CA in 33 CFR 165.1191, Table 1, Item number 15. This safety zone will be in effect from 7 a.m. until 10:30 p.m. on July 4, 2017. Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 25, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13838 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0607]

Safety Zone; Fourth of July Fireworks, City of Martinez, Carquinez Strait, Martinez, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Fourth of July Fireworks display in the City of Martinez in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 11 will be enforced from 9:30 p.m. to 10 p.m. on July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 11 on July 4, 2017. Upon commencement of the 20 minute fireworks display, scheduled to begin at 9:30 p.m. on July 4, 2017, the safety zone will encompass the navigable waters surrounding the land based launch site at Waterfront Park near Martinez, CA within a radius of 560 feet in approximate position 38°01′32″ N., 122°08′24″ W. (NAD 83) for the Fourth of July Fireworks, City of Martinez in 33 CFR 165.1191, Table 1, Item number 11. Upon the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 9:30 p.m. to approximately 10 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notification in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 4, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13851 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0604]

Safety Zone; Red, White, and Tahoe Blue Fireworks, Incline Village, NV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Red, White, and Tahoe Blue Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 19, will be enforced without actual notice from June 30, 2017, until July 4, 2017. For the purposes of enforcement, actual notice will be used from June 28, 2017 through June 30, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Christina Ramirez, Sector San Francisco Waterways Safety Division, U.S. Coast Guard; telephone 415–399–2001, email *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in navigable waters around and under the fireworks barges within a radius of 100 feet during the loading of the fireworks barges at the display location and until the start of the fireworks display. From 12:20 p.m. on June 28, 2017 until 5 p.m. on July 4, 2017 the fireworks barges will be loaded in the vicinity of Incline Beach, near Incline Village, NV at approximate position 39°14′13″ N., 119°57′01″ W. (NAD 83) where they will remain until the commencement of the fireworks display. Upon the commencement of the 35-minute fireworks display, scheduled to start at approximately 9:30 p.m. on July 4, 2017, the safety zone will increase in size to encompass the navigable waters around and under the fireworks barges within a radius of 1,000 feet at approximate position 39°14′13″ N., 119°57′01″ W. (NAD 83) for the Red, White, and Tahoe Blue Fireworks, Incline Village, NV in 33 CFR 165.1191, Table 1, Item number 19. This safety zone will be in effect from 12:20 p.m. on June 28, 2017 until 10:30 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This document is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 23, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13647 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0605]

Safety Zone; Independence Day Fireworks, Kings Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Independence Day Fireworks, Kings Beach, CA in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, number 17, will be enforced from 7 a.m. through 10:30 p.m. on July 3, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, Sector San Francisco Waterways Safety Division, U.S. Coast Guard; telephone 415–399–2001, email *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in navigable waters around and under the fireworks barge within a radius of 100 feet during the loading, transit, and until the start of the fireworks display. From 7 a.m. until 9 a.m. on July 3, 2017, the fireworks barge will be loading pyrotechnics at the Kings Beach Boat Ramp in Kings Beach, CA. From approximately 9 a.m. to 10 a.m. on July 3, 2017, the loaded barge will be towed from the Kings Beach Boat Ramp to the display location off of Kings Beach, CA in approximate position 39°13′59″ N., 120°01′37″ W. (NAD 83) where it will remain until the conclusion of the fireworks display. Upon the commencement of the 15 minute fireworks display, scheduled to begin at 9:30 p.m. on July 3, 2017, the safety zone will increase in size to encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet in approximate position 39°13′59″ N., 120°01′37″ W. (NAD 83) for the Independence Day Fireworks, Kings Beach, CA in 33 CFR 165.1191, Table 1, Item number 17. This safety zone will be in effect from 7 a.m. until 10:30 p.m. on July 3, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notification in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 30, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13839 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0611]

Safety Zone; Delta Independence Day Celebration Fireworks

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Delta Independence Day Celebration Fireworks in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 14 will be enforced from 8 a.m. to 10:30 p.m. July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a 100 foot safety zone around the fireworks barge during the loading, transit, and arrival of the fireworks barge to the display location and until the start of the fireworks display. From 8 a.m. until 9 a.m. on July 4, 2017, the fireworks barge will be loading off of Dutra Corporation Yard in Rio Vista, CA. From approximately 9 a.m. to 2 p.m. on July 4, 2017 the loaded barge will transit from Dutra Corporation Yard to the launch site near Venice Island, CA in approximate position 38°03′21″ N., 121°32′03″ W. (NAD83). The fireworks barge will remain at launch site until the commencement of the fireworks display. Upon the commencement of the 20-minute fireworks display, scheduled to begin at approximately 9:30 p.m. on July 4, 2017, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet in approximate position 38°03′21″

N., 121°32′03″ W. (NAD83) for the Delta Independence Day Celebration Fireworks in 33 CFR 165.1191, Table 1, Item number 14. This safety zone will be in effect from 8 a.m. to 10:30 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 30, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13837 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0468]

RIN 1625–AA00

Safety Zone; Severn River, Sherwood Forest, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Severn River. This action is necessary to provide for the safety of life on the navigable waters of Sherwood Forest near Annapolis, MD, during a fireworks display on July 3, 2017. This action will prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative.

DATES: This rule is effective from 8 p.m. on July 3, 2017, until 10:30 p.m. on July 7, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0468 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Ronald Houck, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On December 29, 2016, the Sherwood Forest Club, Inc. of Sherwood Forest, MD notified the Coast Guard that from 9:15 p.m. to 10 p.m. on July 3, 2017, it will be conducting a fireworks display launched from the end of the Sherwood Forest Club main pier located adjacent to the Severn River, approximately 200 yards east of Brewer Pond in Sherwood Forest, MD. In the event of inclement weather, the fireworks display will be scheduled for July 7, 2017. In response, on April 6, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Special Local Regulations and Safety Zones; Recurring Marine Events and Fireworks Displays Within the Fifth Coast Guard District'' (82 FR 16746). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended May 8, 2017, we received two comments. While the Coast Guard has made the determination to issue a temporary final rule concerning this year's fireworks display, USCG still plans to issue a final rule in the future to cover this recurring event in future years.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with a fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with the fireworks to be used in this July 3, 2017 display will be a safety concern for anyone on the Severn River near the end of the Sherwood Forest Club main pier. The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received two comments on our NPRM published April 6, 2017. Both comments addressed issues not related to this rulemaking. Therefore, there are no changes in the regulatory text of this rule from the proposed rule in the NPRM based on the comments received.

Details of the event were provided to the Coast Guard on May 15, 2017, that allowed the COTP to reassess the potential hazards associated with the fireworks to be used in this July 3, 2017 display. The area of the safety zone at the fireworks discharge site located at end of the Sherwood Forest Club main pier, listed in the Table to 33 CFR 165.506 under Coast Guard Sector Maryland-National Capital Region—COTP Zone as No. (b.)27, is reduced from a 200 yards radius to a 150 yards radius. As a result, there is one change in the regulatory text of this rule from the proposed rule in the NPRM. The safety zone will be reduced in size from 200 yards from the center point located at 39°01′54.0″ N., longitude 076°32′41.8″ W. to a 150 yard radius.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. 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 not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Severn River for 2½ hours during the evening when vessel traffic is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule might affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting approximately 2½ hours that will prohibit entry within 150 yards of a fireworks discharge site at the end of the Sherwood Forest pier. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 19133 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0468 to read as follows:

§ 165.0468 Safety Zone; Severn River, Sherwood Forest, MD.

(a) *Definitions.* As used in this section:

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

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Maryland-National Capital Region to assist in enforcing the safety zone described in paragraph (a) of this section.

(b) *Location.* The following area is a safety zone: All waters of the Severn River, within a 150 yards radius of a fireworks discharge site located at the end of Sherwood Forest Club main pier in approximate position latitude 39°01′54.0″ N., longitude 076°32′41.8″ W., Sherwood Forest, MD. All coordinates refer to datum NAD 1983.

(c) *Regulations.* The general safety zone regulations found in subpart C of this part apply to the safety zone created by this section.

(1) All persons are required to comply with the general regulations governing safety zones found in § 165.23.

(2) Entry into or remaining in this safety zone is prohibited unless authorized by the Coast Guard Captain of the Port Maryland-National Capital Region. All vessels underway within this safety zone at the time it is implemented shall depart the safety zone.

(3) Persons desiring to transit the area of the safety zone must first obtain authorization from the Captain of the Port Maryland-National Capital Region or designated representative. To request permission to enter or transit the regulated area, the Captain of the Port Maryland-National Capital Region or designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed. If permission is granted to enter the safety zone, all persons and vessels must comply with the instructions of the Captain of the Port Maryland-National Capital Region or designated representative and proceed as directed while in the zone.

(4) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(d) *Enforcement period.* This section will be enforced from 8 p.m. through 10:30 p.m. on July 3, 2017, and if necessary due to inclement weather, from 8 p.m. through 10:30 p.m. on July 7, 2017.

Dated: June 22, 2017.

M.W. Batchelder,

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

[FR Doc. 2017–13767 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0502]

RIN 1625–AA00

Safety Zone; Navy Underwater Detonation (UNDET) Exercise, Apra Outer Harbor, GU

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within Apra Outer Harbor, Guam. The safety zone will encompass a U.S. Navy underwater detonation (UNDET) exercise. The Coast Guard believes this safety zone regulation is necessary to protect the public and exercise participants within the affected area from possible safety hazards associated with the exercise. This safety zone will impact a small designated area of navigable waters in Apra Harbor for 8 hours or less. With the exception of exercise participants, entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port Guam.

DATES: This rule is effective from 8 a.m. through 4 p.m. on July 13th, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0502 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Robin Branch, Sector Guam, U.S. Coast Guard; telephone (671) 355–4835, email *wwmguam@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

After the Coast Guard analyzed the scope and potential impacts associated with a temporary safety zone being established, the Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to public interest. To delay implementation of the safety zone past the exercise date of July 13th, 2017 to publish and seek public comment is impracticable as it would unavoidably prevent the Coast Guard from ensuring the safety of the public and exercise participants from potential hazards associated with the exercise. It is for the same reason good cause exists under the public interest exception to the required public comment period. It is in the public's interest the safety zone be established prior to notice and comment to ensure the safety zone is in place for the UNDET exercise on July 13th, 2017.

For the same reasons as noted above, we are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Due to the potential dangers associated with the UNDET exercise, delaying the effective period of this safety zone beyond July 13th, 2017 would be impracticable and contrary to public interest. The temporary final rule and resulting restricted navigation area established by this rulemaking relates to the establishment of the safety zone itself. It does not address or regulate the UNDET exercise. The U.S. Navy environmental impact statement and public involvement for the UNDET activity is available at *http://mitt-eis.com/.*

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Guam concurs with the U.S. Navy that potential hazards associated with the UNDET exercise on July 13th, 2017 may be a safety concern for anyone within a 700-yard radius above and below the surface in the area of the operation. This rule is needed to protect the public, exercise participants and vessels in the navigable waters within the safety zone during the exercise. Mariners and divers

approaching too close to such exercises could potentially be exposed to hazardous conditions or place the exercise participants at risk.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 a.m. through 4 p.m. on July 13th, 2017. The safety zone will cover all navigable waters within 700-yards above and below the surface of the water around the UNDET exercise. The duration of the zone is intended to protect the public, exercise participants and vessels in navigable waters during the exercise. No vessel or person, with the exception of exercise participants, will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of waters in the outer harbor for 8 hours or less. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone. Further, the rule allows vessels and persons to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that the establishment of a safety zone is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting up to eight hours that will prohibit entry within 700-yards above and below the surface of the UNDET exercise. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without

jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and record-keeping requirements, Security measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14–0502 to read as follows:

165. T14–0502 Safety Zone; Navy UNDET Exercise, Apra Outer Harbor, GU.

(a) *Location.* The following areas, within the Captain of the Port (COTP) Guam Zone (See 33 CFR 3.70–15), from the surface of the water to the ocean floor, are safety zones:

Apra Outer Harbor, Guam July 13, 2017. All waters above and below the surface bounded by a circle with a 700-yard radius centered at 13 degrees 27 minutes 42 seconds North Latitude and 144 degrees 38 minutes 30 seconds East Longitude, (NAD 1983).

(b) *Effective period.* This section is effective from 8 a.m. through 4 p.m. on July 13th, 2017, unless canceled earlier by the COTP Guam.

(c) *Regulations.* The general regulations governing safety zones contained in 33 CFR 165.23 apply. No vessels, with the exception of exercise participants may enter or transit the safety zone and no persons in the water, with the exception of exercise participants may enter or transit the safety zone unless authorized by the COTP Guam or a designated representative thereof.

(d) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer, and any other COTP Guam representative permitted by law, may enforce this temporary safety zones.

(e) *Waiver.* The COTP Guam may waive any of the requirements of this section for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime safety and security.

(f) *Penalties.* Vessels or persons violating this rule are subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192.

Dated: June 8, 2017.

James B. Pruett,

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

[FR Doc. 2017–13853 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0612]

Safety Zone; Fourth of July Fireworks, Glenbrook NV

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Fourth of July Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect the life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 16 will be enforced from 7 a.m. through 10:30 p.m. on July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in navigable waters around and under a fireworks barge within a radius of 100 feet during the loading of the fireworks barge and until the start of the fireworks display. From 7 a.m. until 8 a.m. on July 4, 2017, the fireworks barge will be loading pyrotechnics at the launch site in Glenbrook Bay in approximate position 39°05′18″ N., 119°56′34″ W. (NAD 83). The fireworks barge will remain at the launch site in Glenbrook Bay in approximate position 39°05′18″ N., 119°56′34″ W. (NAD 83) until the commencement of the fireworks display. Upon the commencement of the 20 minute fireworks display, scheduled to begin at approximately 9:30 p.m. on July 4, 2017, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet in approximate position 39°05′18″ N., 119°56′34″ W. (NAD 83). Upon the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 7 a.m. until approximately 10:30 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice of enforcement is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notification in the **Federal Register,** the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 23, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13844 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0616]

Safety Zone; Commencement Bay, Tacoma, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone regulations for the Tacoma Freedom Fair Air Show on Commencement Bay from 1:30 p.m. July 4, 2017, until 12:30 a.m. on July 5, 2017. This action is necessary to ensure the safety of the public from inherent dangers associated with these annual aerial displays. During the enforcement period, no person or vessel may enter or transit this safety zone unless authorized by the Captain of the Port or her designated representative.

DATES: The regulations in 33 CFR 165.1305 will be enforced from 1:30 p.m. July 4, 2017, until 12:30 a.m. on July 5, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Petty Officer Zachary Spence, Sector Puget Sound Waterways Management Division, Coast Guard; telephone (206) 217–6051, email *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1305 from 1:30 p.m. July 4, 2017 until 12:30 a.m. July 5, 2017 unless canceled sooner by the Captain of the Port Puget Sound. It is necessary to start the safety zone 30 minutes sooner since the Tacoma Freedom Fair Air Show will begin at 1:30 p.m. instead of 2 p.m. This action is being taken to provide for the safety of life on navigable waterways during the air show.

The safety zone resembles a rectangle protruding from the shoreline along Ruston Way and will be marked by the event sponsor. The specific coordinates of the safety zone location is listed in 33 CFR 165.1305.

As specified in § 165.1305(c), during the enforcement period, no vessel may transit this regulated area without approval from the Captain of the Port Sector Puget Sound (COTP) or a COTP designated representative. The Captain of the Port may be assisted by other federal, state and local law enforcement agencies in enforcing this regulation.

This notice of enforcement is issued under authority of 33 CFR 165.1305 and 5 U.S.C. 552 (a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advanced notification of the safety zone via the Local Notice to Mariners and marine information broadcasts on the day of the event. If the COTP determines that the safety zone need not be enforced for the full duration stated in this notice of enforcement, she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: June 26, 2017.

L.A. Sturgis,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2017–13680 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0609]

Safety Zone; Fourth of July Fireworks, City of Sausalito, San Francisco Bay, Sausalito, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Fourth of July Fireworks, City of Sausalito in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 10 will be enforced from 9 a.m. to 10 p.m. on July 4, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Christina Ramirez, U.S. Coast Guard Sector San Francisco; telephone (415) 399–2001 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone extending around and under the fireworks barge within a radius of 100 feet during the loading, transit, and arrival of the fireworks barge to the display location until the start of the fireworks display.

From 9 a.m. until 3 p.m. on July 4, 2017, the fireworks barge will be loading pyrotechnics off of Pier 50 in San Francisco, CA. The fireworks barge will remain at the pier until its transit to the display location. From 6:30 p.m. to 8 p.m. on July 4, 2017 the loaded fireworks barge will transit from Pier 50 to the launch site near Sausalito, CA in approximate position 37°51′31″ N., 122°28′28″ W. (NAD83) where it will remain until the conclusion of the scheduled fireworks display.

Upon the commencement of the fireworks display at approximately 9:15 p.m. on July 4, 2017, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius of 1,000 feet in approximate position 37°51′31″ N., 122°28′28″ W. (NAD83) for the Fourth of July Fireworks, City of Sausalito in 33 CFR 165.1191, Table 1, Item number 10. This safety zone will be in effect from 9 a.m. to 10 p.m. on July 4, 2017.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 4, 2017.

Anthony J. Ceraolo,

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

[FR Doc. 2017–13852 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Parts 300 and 303

RIN 1820–AB74

Assistance to States for the Education of Children With Disabilities and Preschool Grants for Children With Disabilities Program; Early Intervention Program for Infants and Toddlers With Disabilities

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

ACTION: Final regulations.

SUMMARY: The Secretary of Education (Secretary) amends the regulations implementing Parts B and C of the Individuals with Disabilities Education Act (IDEA). These conforming changes are needed to implement statutory amendments made to the IDEA by the Every Student Succeeds Act (ESSA), enacted on December 10, 2015. These regulations remove and revise IDEA definitions based on changes made to the definitions in the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the ESSA, and also update several State eligibility requirements to reflect amendments to the IDEA made by the ESSA. They also update relevant cross-references in the IDEA regulations to sections of the ESEA to reflect changes made by the ESSA. These regulations also include several technical corrections to previously published IDEA Part B regulations.

DATES: These final regulations are effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Mary Louise Dirrigl, U.S. Department of Education, 550 12th Street SW., Potomac Center Plaza, Room 5156, Washington, DC 20202–2641. Telephone: (202) 245–7324 or by email: *Mary.Louise.Dirrigl@ed.gov.* If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action: Enacted December 10, 2015, the ESSA [1] reauthorized the ESEA, which provides Federal funds to improve elementary and secondary education in the Nation's public schools. The ESSA also made certain changes to sections 602 and 611 through 614 of the IDEA. Consequently, we are amending the IDEA regulations in parts 300 and 303 to reflect these changes.

Summary of the Major Provisions of This Regulatory Action: For the IDEA regulations in parts 300 and 303, these regulations:

- Revise the definition of the term ''charter school'' in § 300.7 to update the statutory reference to the ESEA's amended definition of that term.
- Remove the definition of the term ''core academic subjects'' in § 300.10, the definition of ''highly qualified special education teachers'' in § 300.18, and the definition of ''scientifically based research'' in §§ 300.35 and 303.32 because these terms have been removed from the ESEA.
- Revise the term ''Limited English proficient'' in § 300.27 to reflect the revisions to the term ''English learner'' in section 8101 of the ESEA.
- Revise § 300.102(a)(3)(iv) to incorporate the definition of ''regular high school diploma'' in section 8101(43) of the ESEA.
- Move the qualification requirements for special education teachers from § 300.18(b)(1) and (2) to § 300.156(c).
- Revise § 300.160(c) to reflect amendments made to the IDEA by the ESSA that clarify that guidelines and alternate assessments to measure academic progress under title I of the ESEA apply only to children with disabilities who are students with the most significant cognitive disabilities, whose achievement is measured against alternate academic achievement standards if a State has adopted such standards as permitted under section 1111(b)(1)(E) of the ESEA.
- Revise paragraph (b)(4)(xi) of § 300.704 (State-level activities), regarding the provision of technical assistance to schools and local educational agencies (LEAs) implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA on the basis of consistent underperformance of the disaggregated subgroup of children with disabilities, to include direct student services described in section 1003A(c)(3) of the ESEA to children with disabilities.

Part 300 Regulatory Changes

Subpart A—General

Definitions Used in This Part

We are revising the definition of ''charter school'' in § 300.7 by removing the phrase ''section 5210(1)'' and replacing it with ''section 4310(2).'' We are revising the authority citation for § 300.7 by removing ''20 U.S.C. 7221i(1)'' and replacing it with ''20 U.S.C. 7221i(2).''

We are removing the definition of ''core academic subjects'' in § 300.10 and reserving § 300.10. This change is consistent with section 9215(ss)(1)(A) of the ESSA, which eliminated section 602(4) of the IDEA.

Consistent with section 9215(ss)(1)(B) of the ESSA, we are revising the definition of ''excess cost'' in § 300.16. Specifically, we are revising the cross-reference to the ESEA in § 300.16(a)(3) to read ''under part A of title III of the ESEA.''

We are removing the definition of ''highly qualified special education teachers'' in § 300.18, consistent with section 9214(d)(1) of the ESSA, which eliminated section 602(10) of the IDEA, and we are reserving § 300.18. Consequently, we are removing the references to § 300.18 in §§ 300.138(a)(1) and 300.146(b) and adding a reference to § 300.156(c) in § 300.138(a)(1), as explained below. Based on the amendments made to the IDEA by section 9214(d)(2)(A) of the ESSA, as discussed in Subpart B, we are moving § 300.18(b)(1) and (2), regarding qualifications for special education teachers, to § 300.156(c). Consistent with changes made by section 9214(d)(2)(B) and (C) to section 612(a)(14)(D) and (E) of the IDEA, we are also removing references to the term ''highly qualified'' in § 300.156(d) and (e) and replacing them with references to personnel ''who meet the applicable requirements described in paragraph (c) of this section.''

Consistent with section 9215(ss)(1)(C) of the ESSA, which amended section 602(18) of the IDEA, we are revising the definition of ''Limited English proficient'' in § 300.27 to adopt the meaning given to the term ''English learner'' in section 8101 of the ESEA.

Consistent with section 8002(1) of the ESEA, we are removing the definition of ''scientifically based research'' in § 300.35 because this definition has been removed from the ESEA. Section 300.35 is reserved. However, we are retaining references to ''scientifically based research'' in §§ 300.604(a)(1)(ii) and 300.704(b)(4)(xi), because these references were retained in sections 616(e)(1)(A)(ii) and 611(e)(2)(C)(xi), respectively.

We are revising the following cross-references to definitions:

- The cross-reference to the definition of ''special education'' in § 300.105(a)(1) is changed from § 300.36 to § 300.39, and from § 300.38 to § 300.39 in § 300.115(b)(1).

[1] Unless otherwise indicated, citations to the ESEA refer to the ESEA, as amended by the ESSA.

• The cross-reference to the definition of ''supplementary aids and services'' in § 300.105(a)(3) is changed from § 300.38 to § 300.42, and from § 300.41 to § 300.42 in § 300.154(b)(1)(i).

• The cross-reference to the definition of ''transition services'' in § 300.154(b)(1)(i) is changed from § 300.42 to § 300.43.

Subpart B—State Eligibility

Free Appropriate Public Education (FAPE) Requirements

We are revising § 300.102(a)(3)(iv) to incorporate the definition of ''regular high school diploma'' currently included in section 8101(43) of the ESEA. The term means the standard high school diploma awarded to the preponderance of students in the State that is fully aligned with State standards, or a higher diploma, except that a regular high school diploma shall not be aligned to the alternate academic achievement standards described in section 1111(b)(1)(E) of the ESEA. A regular high school diploma does not include a recognized equivalent of a diploma, such as a general equivalency diploma, certificate of completion, certificate of attendance, or similar lesser credential. We are making this conforming change to ensure that ''regular high school diploma'' has the same meaning under the IDEA and the ESEA, and the definition is consistently applied under both programs. We are also updating the authority citation to reflect this change.

Additional Eligibility Requirements

Consistent with section 9214(d)(2)(A) of the ESSA, we are revising § 300.156(c) by removing the language indicating that each person employed as a public school special education teacher in the State must be highly qualified by the deadline established in section 1119(a)(2) of the ESEA. In its place at § 300.156(c), we are adding language from the current definition of ''highly qualified'' in § 300.18(b)(1). The revisions are needed to clarify that the IDEA, as amended by the ESSA, retains the same requirements as in current § 300.18(b)(1) governing the qualifications of special education teachers. Additionally, consistent with section 9214(d)(2)(A) of the ESSA, we are retaining the requirements in current § 300.18(b)(2), regarding participation in an alternate route to certification as a special educator. The retention of these requirements is consistent with amendments to section 612(a)(14)(C)(i) of the IDEA, which require that an alternate route to certification as a special educator meets the minimum requirements described in 34 CFR 200.56(a)(2)(ii), as such section was in effect on November 28, 2008. Because 34 CFR 200.56(a)(2)(ii), as in effect on November 28, 2008, included the language in current § 300.18(b)(2), we are moving the language in current § 300.18(b)(2) to new § 300.156(c)(2). Additionally, consistent with amendments to section 612(a)(14)(D) and (E) of the IDEA made by section 9214(d)(2)(B) and (C) of the ESSA, we are removing references to ''highly qualified'' in paragraphs (d) and (e) of § 300.156 and replacing them with references to personnel ''who meet the applicable requirements described in paragraph (c) of this section.''

Consistent with section 9215(ss)(3)(A) of the ESSA, which amended section 612(a)(15) of the IDEA (Performance goals and indicators), we are making the following changes to § 300.157. Consistent with section 9215(ss)(3)(A)(i) of the ESSA, which amended section 612(a)(15)(A)(ii) of the IDEA, we are replacing § 300.157(a)(2) in its entirety with the language ''Are the same as the State's long-term goals and measurements of interim progress for children with disabilities under section 1111(c)(4)(A)(i) of the ESEA.'' Consistent with amendments to section 612(a)(15)(B) made by section 9215(ss)(3)(A)(ii) of the ESSA, we are also revising § 300.157(b) by replacing the language ''including measurable annual objectives for progress by children with disabilities under section 1111(b)(2)(C)(v)(II)'' with ''including measurements of interim progress for children with disabilities under section 1111(c)(4)(A)(i).''

We are making a number of amendments to §§ 300.160(c) through (f) to address amendments made by section 9215(ss)(3)(B) of the ESSA to section 612(a)(16)(C)(ii) of the IDEA, as well as changes made by the ESSA to section 1111(b)(2)(D) of the ESEA, which affect current (d), (e), and (f) of § 300.160. We are changing the title of § 300.160(c) from ''Alternate Assessments'' to ''Alternate Assessments Aligned with Alternate Academic Achievement Standards for Students with the Most Significant Cognitive Disabilities.'' We are adding the phrase ''children with disabilities who are students with the most significant cognitive disabilities'' in § 300.160(c)(1) with respect to State guidelines for participation in alternate assessments, because section 9215(ss)(3)(B) of the ESSA clarifies that the State guidelines referred to in section 612(a)(16)(C)(i) of the IDEA apply only to participation of children with disabilities who are students with the most significant cognitive disabilities in alternate assessments aligned with alternate academic achievement standards as permitted under section 1111(b)(1)(E) of the ESEA, if those children cannot take regular assessments, even with accommodations as indicated in their respective individualized education programs (IEPs).

Consistent with section 9215(ss)(3)(B) of the ESSA, which amended section 612(a)(16)(C)(ii) of the IDEA, we are also reorganizing § 300.160(c)(2) for greater clarity and to ensure consistency with 34 CFR 200.6(c) of the regulations for title I, part A of the ESEA. These changes will clarify that if a State has adopted alternate academic achievement standards as permitted under section 1111(b)(1)(E) of the ESEA and 34 CFR 200.1(d) of the regulations for title I, part A of the ESEA, the State must conduct alternate assessments that measure the achievement of children with disabilities who are students with the most significant cognitive disabilities against those standards. Consistent with amendments made to section 612(a)(16)(C)(ii) of the IDEA by section 9215(ss)(3)(B) of the ESSA, we are replacing the phrase ''the State's challenging academic content standards and challenging student academic achievement standards'' with ''challenging State academic content standards under section 1111(b)(1) of the ESEA and alternate academic achievement standards under section 1111(b)(1)(E) of the ESEA.'' Accordingly, § 300.160(c)(2)(iii) is removed, because the statutory amendments that form the basis for the above regulatory changes clarify that in assessing the academic progress of children with disabilities under title I, part A of the ESEA, the only alternate assessments permitted under the IDEA and title I of the ESEA are alternate assessments aligned with alternate academic achievement standards for children with disabilities who are students with the most significant cognitive disabilities under section 1111(b)(2)(D) of the ESEA. We are amending § 300.160(c)(3) by adding a reference to section 1111(b)(1)(E)(ii) of the ESEA and changing the title I, part A regulatory reference to § 200.6(c)(6) to reinforce that States are prohibited from adopting modified academic achievement standards or any other alternate academic achievement standards that do not meet the requirements in section 1111(b)(1)(E) of the ESEA for any students with disabilities under section 602(3) of the IDEA.

Consistent with section 1111(b)(2)(D)(i)(II) of the ESEA, and 34

CFR 200.6(d)(2), we are amending § 300.160(d) (Explanation to IEP Teams). We are adding new § 300.160(d)(1) to read, ''A State (or in the case of a district-wide assessment, an LEA) must provide to IEP teams a clear explanation of the differences between assessments based on grade-level academic achievement standards and those based on alternate academic achievement standards, including any effects of State and local policies on a student's education resulting from taking an alternate assessment aligned with alternate academic achievement standards, such as how participation in such assessments may delay or otherwise affect the student from completing the requirements for a regular high school diploma.'' Consistent with section 1111(b)(2)(D)(i)(VII) of the ESEA, and 34 CFR 200.6(d)(4), we have added new § 300.160(d)(2), which reads, ''A State (or in the case of a district-wide assessment, an LEA) must not preclude a student with the most significant cognitive disabilities who takes an alternate assessment aligned with alternate academic achievement standards from attempting to complete the requirements for a regular high school diploma.'' Even though this language is now reflected in 34 CFR 200.6(d)(2) and (4), we believe this is important information for IEP teams to have in ensuring that students with the most significant cognitive disabilities taking alternate assessments aligned with alternate academic achievement standards receive the special education and related services that they need to enable them to be involved and make progress in the general education curriculum that is aligned with the State's challenging academic content standards for the grade in which the student is enrolled. Similarly, we believe it is important for parents to be fully informed of the possible implications of their child's participation in alternate assessments aligned with alternate academic achievement standards. Therefore, consistent with section 1111(b)(2)(D)(i)(II) of the ESEA, and 34 CFR 200.6(d)(3), we have revised § 300.160(e) (Inform parents) to read, ''A State (or in the case of a district-wide assessment, an LEA) must ensure that parents of students selected to be assessed using an alternate assessment aligned with alternate academic achievement standards under the State's guidelines referred to in paragraph (c)(1) are informed, consistent with § 200.2(e), that their child's achievement will be measured based on alternate academic achievement standards, and how participation in such assessments may delay or otherwise affect the student from completing the requirements for a regular high school diploma.'' This revised language is also consistent with 34 CFR 200.6(d)(3), implementing title I, part A of the ESEA.

Consistent with section 612(a)(16)(C) of the IDEA and section 1111(b)(1)(E)(ii) of the ESEA, we are revising § 300.160(f) to make clear that school year 2016–2017 is the last school year for which States may report on the participation and performance of children with disabilities taking alternate assessments based on grade-level achievement standards. We are also correcting an inadvertent error in § 300.160(f)(3), regarding participation in assessments, that was included in the August 21, 2015 regulations governing title I, part A of the ESEA. See Improving the Academic Achievement of the Disadvantaged; Assistance to States for the Education of Children With Disabilities. 80 FR 50773. We are replacing school years prior to ''2015–2016'' with school years prior to ''2016–2017.'' This correction clarifies that school year 2015–2016, not school year 2014–2015, was the last school year in which States were permitted to administer alternate assessments based on modified academic achievement standards. We have also removed the words ''if any'' from § 300.160(f)(4), because the only alternate assessments that States may conduct to assess academic progress under title I of the ESEA are alternate assessments aligned with alternate academic achievement standards for students with the most significant cognitive disabilities. We are also changing the words ''based on'' to ''aligned with'' in paragraphs (f)(3) and (4) of § 300.160 to be consistent with the language used elsewhere in § 300.160(c) referring to alternate assessments conducted under this section.

Subpart C—Local Educational Agency Eligibility

Consistent with section 9215(ss)(4) of the ESSA, which amended section 613(a)(3) of the IDEA, we are revising § 300.207, regarding personnel development, by removing the reference to ''section 2122 of the ESEA'' and replacing it with ''section 2102(b) of the ESEA.''

Subpart D—Evaluations, Eligibility Determinations, Individualized Education Programs, and Educational Placements

Evaluations and Reevaluations

Consistent with section 9215(ss)(5) of the ESSA, which amended section 614(b)(5)(A) of the IDEA, we are revising § 300.306(b)(1)(i), regarding determination of eligibility, by inserting the phrase ''as such section was in effect on the day before the date of enactment of the Every Student Succeeds Act (December 9, 2015)'' after ''ESEA.''

Development of IEP

We are correcting an inadvertent error in § 300.324(d)(2)(ii) (Children with disabilities in adult prisons) by changing the least restrictive environment reference from § 300.112 to § 300.114.

Subpart G—Authorization, Allotment, Use of Funds, and Authorization of Appropriations

Allotments, Grants, and Use of Funds

Consistent with section 9215(ss)(2)(A) and (B) of the ESSA, which amended section 611(e)(2)(C) and (e)(3)(C)(ii)(I)(bb) of the IDEA, we are making the following revisions. We are revising § 300.704(b)(4) (Other State-level activities) as follows:

- Removing ''section 6111 of the ESEA'' from paragraph (x) and replacing it with ''section 1201 of the ESEA.''
- Revising paragraph (xi) regarding the provision of technical assistance to schools and LEAs by removing ''including supplemental educational services as defined in section 1116(e) of the ESEA to children with disabilities, in schools or LEAs identified for improvement under section 1116 of the ESEA on the sole basis of the assessment results of the disaggregated subgroup of children with disabilities'' and replacing it with ''including direct student services described in section 1003A(c)(3) of the ESEA to children with disabilities, to schools or LEAs implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA on the basis of consistent underperformance of the disaggregated subgroup of children with disabilities.''
- Replacing the phrase ''to meet or exceed the objectives established by the State under section 1111(b)(2)(G) of the ESEA'' with ''based on the challenging academic standards described in section 1111(b)(1) of the ESEA.''
- Finally, we are revising § 300.704(c)(3)(i)(A)(*2*), regarding the LEA high cost fund, by changing the ESEA reference from section 9101 to section 8101.

Part 303 Regulatory Changes

Subpart A—General

Definitions Used in This Part

Consistent with section 8002(1) of the ESEA, we are removing the definition of

''scientifically based research'' from § 303.32, because this definition has been removed from the ESEA. Section 303.32 is reserved. The definition of ''scientifically based research'' was adopted in the 2011 regulations under Part C of the IDEA to cross-reference the same definition under the ESEA. However, the term ''scientifically based research'' is still retained and applies to § 303.112 of the Part C regulations regarding the State's responsibility to make early intervention services available under section 635(a)(2) of the IDEA. See 76 FR 60140, 60163–60164 (Sept. 28, 2011).

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new regulation that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, it must identify two deregulatory actions. For Fiscal Year 2017, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. The final regulations are not a significant regulatory action. Therefore, the requirements of Executive Order 13771 do not apply.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these final regulations only upon a reasoned determination that their benefits will justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these final regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Potential Costs and Benefits

Under Executive Order 12866, we have assessed the potential costs and benefits of this regulatory action and have determined that these regulations will not impose additional costs to States and LEAs or to the Federal government. These regulations do not impose additional costs or administrative burdens because States will be in the process of developing and revising their regulations implementing title I of the ESEA to conform with the changes made by the ESSA. We believe any additional costs imposed on States by these final regulations will be negligible, primarily because they reflect technical changes which do not impose additional burden. Moreover, we believe any costs will be significantly outweighed by the potential benefits of ensuring consistency among the implementation of the IDEA and ESSA requirements for children with disabilities.

Waiver of Rulemaking and Delayed Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, the APA provides that an agency is not required to conduct notice- and-comment rulemaking when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B)). There is good cause to waive rulemaking here as unnecessary.

Rulemaking is ''unnecessary'' in those situations in which ''the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Utility Solid Waste Activities Group* v. *EPA,* 236 F.3d 749, 755 (D.C. Cir. 2001), *quoting* U.S. Department of Justice, *Attorney General's Manual on the Administrative Procedure Act* 31 (1947) and *South Carolina* v. *Block,* 558 F. Supp. 1004, 1016 (D.S.C. 1983). These regulations implement the technical amendments made to the IDEA by the ESSA and include revisions made for consistency with the statute.

The APA also generally requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner (5 U.S.C. 553(d)(3)). Again, because these final regulations include only conforming changes and technical corrections, there is good

cause to make them effective on the day they are published.

Paperwork Reduction Act of 1995

These regulations do not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of the Department's specific plans and actions for this program.

Assessment of Educational Impact

Based on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register.** Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Parts 300 and 303

Administrative practice and procedure, Education of individuals with disabilities, Elementary and secondary education, Equal educational opportunity, Grant programs—education, Privacy, Private schools, Reporting and recordkeeping requirements.

Dated: June 27, 2017.

Betsy DeVos,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary amends parts 300 and 303 of title 34 of the Code of Federal Regulations as follows:

PART 300—ASSISTANCE TO STATES FOR THE EDUCATION OF CHILDREN WITH DISABILITIES

■ 1. The authority citation for part 300 is revised to read as follows:

Authority: 20 U.S.C. 1221e–3, 1406, 1411–1419, and 3474, unless otherwise noted.

§ 300.7 [Amended]

■ 2. Section 300.7 is amended by removing the phrase ''section 5210(1)'' and adding in its place ''section 4310(2)'' and by removing the authority citation ''20 U.S.C. 7221i(1)'' and adding in its place ''20 U.S.C. 7221i(2)''.

§ 300.10 [Removed and Reserved]

■ 3. Remove and reserve § 300.10.

§ 300.16 [Amended]

■ 4. Section 300.16 is amended in paragraph (a)(3) by removing the words ''Parts A and B'' and adding in its place ''Part A''.

§ 300.18 [Removed and Reserved]

■ 5. Remove and reserve § 300.18.

§ 300.27 [Amended]

■ 6. Section 300.27 is amended by removing the phrase ''in section 9101(25) of the ESEA'' and adding in its place '''English learner' in section 8101 of the ESEA''.

§ 300.35 [Removed and Reserved]

■ 7. Remove and reserve § 300.35.

■ 8. Section 300.102 is amended by revising paragraph (a)(3)(iv) and by revising the authority citation to read as follows:

§ 300.102 Limitation—exception to FAPE for certain ages.

(a)* * *

(3)* * *

(iv) As used in paragraphs (a)(3)(i) through (iii) of this section, the term *regular high school diploma* means the standard high school diploma awarded to the preponderance of students in the State that is fully aligned with State standards, or a higher diploma, except that a regular high school diploma shall not be aligned to the alternate academic achievement standards described in section 1111(b)(1)(E) of the ESEA. A regular high school diploma does not include a recognized equivalent of a diploma, such as a general equivalency diploma, certificate of completion, certificate of attendance, or similar lesser credential.

* * * * *

Authority: 20 U.S.C. 1412(a)(1)(B)–(C) and 7801(43).

§ 300.105 [Amended]

■ 9. Section 300.105 is amended:

■ A. In paragraph (a)(1) by removing ''§ 300.36'' and adding in its place ''§ 300.39''.

■ B. In paragraph (a)(3) by removing ''§ 300.38'' and adding in its place ''§ 300.42''.

§ 300.115 [Amended]

■ 10. Section 300.115 is amended in paragraph (b)(1) by removing ''§ 300.38'' and adding in its place ''§ 300.39''.

§ 300.138 [Amended]

■ 11. Section 300.138 is amended in paragraph (a)(1) by removing the phrase ''highly qualified special education teacher requirements of § 300.18'' and adding in its place ''special education teacher qualification requirements in § 300.156(c)''.

§ 300.146 [Amended]

■ 12. Section 300.146 is amended in paragraph (b) by removing ''§ 300.18 and''.

§ 300.154 [Amended]

■ 13. Section 300.154 is amended in paragraph (b)(1)(i) by removing ''§ 300.41'' and ''§ 300.42'' and adding in their place ''§ 300.42'' and ''§ 300.43'', respectively.

■ 14. Section 300.156 is amended:

■ A. By revising paragraph (c).

■ B. In paragraph (d) by removing the term ''highly qualified'' and adding in its place ''who meet the applicable requirements described in paragraph (c) of this section'' after the word ''personnel''.

■ C. In paragraph (e) by removing the phrase ''be highly qualified'' and adding in its place ''meet the applicable requirements described in paragraph (c) of this section''.

The revision reads as follows:

§ 300.156 Personnel qualifications.

* * * * *

(c) *Qualifications for special education teachers.* (1) The qualifications described in paragraph (a) of this section must ensure that each person employed as a public school special education teacher in the State who teaches in an elementary school, middle school, or secondary school—

(i) Has obtained full State certification as a special education teacher (including certification obtained through an alternate route to certification as a special educator, if such alternate route meets minimum requirements described in 34 CFR 200.56(a)(2)(ii) as such section was in effect on November 28, 2008), or passed the State special education teacher licensing examination, and holds a license to teach in the State as a special education teacher, except that when used with respect to any teacher teaching in a public charter school, the teacher must meet the certification or licensing requirements, if any, set forth in the State's public charter school law;

(ii) Has not had special education certification or licensure requirements waived on an emergency, temporary, or provisional basis; and

(iii) Holds at least a bachelor's degree.

(2) A teacher will be considered to meet the standard in paragraph (c)(1)(i) of this section if that teacher is participating in an alternate route to special education certification program under which—

(i) The teacher—

(A) Receives high-quality professional development that is sustained, intensive, and classroom-focused in order to have a positive and lasting impact on classroom instruction, before and while teaching;

(B) Participates in a program of intensive supervision that consists of structured guidance and regular ongoing support for teachers or a teacher mentoring program;

(C) Assumes functions as a teacher only for a specified period of time not to exceed three years; and

(D) Demonstrates satisfactory progress toward full certification as prescribed by the State; and

(ii) The State ensures, through its certification and licensure process, that the provisions in paragraph (c)(2)(i) of this section are met.

* * * * *

■ 15. Section 300.157 is amended:

■ A. By revising paragraph (a)(2).

■ B. In paragraph (b) by removing ''including measurable annual objectives for progress by children with disabilities under section 1111(b)(2)(C)(v)(II)'' and adding in its place ''including measurements of interim progress for children with disabilities under section 1111(c)(4)(A)(i)''.

The revision reads as follows:

§ 300.157 Performance goals and indicators.

* * * * *

(a) * * *

(2) Are the same as the State's long-term goals and measurements of interim progress for children with disabilities under section 1111(c)(4)(A)(i) of the ESEA.

* * * * *

■ 16. Section 300.160 is amended by revising paragraphs (c) through (f) to read as follows:

§ 300.160 Participation in assessments.

* * * * *

(c) *Alternate assessments aligned with alternate academic achievement standards for students with the most significant cognitive disabilities.* (1) If a State has adopted alternate academic achievement standards for children with disabilities who are students with the most significant cognitive disabilities as permitted in section 1111(b)(1)(E) of the ESEA, the State (or, in the case of a district-wide assessment, an LEA) must develop and implement alternate assessments and guidelines for the participation in alternate assessments of those children with disabilities who cannot participate in regular assessments, even with accommodations, as indicated in their respective IEPs, as provided in paragraph (a) of this section.

(2) For assessing the academic progress of children with disabilities who are students with the most significant cognitive disabilities under title I of the ESEA, the alternate assessments and guidelines in paragraph (c)(1) of this section must—

(i) Be aligned with the challenging State academic content standards under section 1111(b)(1) of the ESEA and alternate academic achievement standards under section 1111(b)(1)(E) of the ESEA; and

(ii) Measure the achievement of children with disabilities who are students with the most significant cognitive disabilities against those standards.

(3) Consistent with section 1111(b)(1)(E)(ii) of the ESEA and 34 CFR 200.6(c)(6), a State may not adopt modified academic achievement standards or any other alternate academic achievement standards that do not meet the requirements in section 1111(b)(1)(E) of the ESEA for any children with disabilities under section 602(3) of the IDEA.

(d) *Explanation to IEP Teams.* A State (or in the case of a district-wide assessment, an LEA) must—

(1) Provide to IEP teams a clear explanation of the differences between assessments based on grade-level academic achievement standards and those based on alternate academic achievement standards, including any effects of State and local policies on a student's education resulting from taking an alternate assessment aligned with alternate academic achievement standards, such as how participation in such assessments may delay or otherwise affect the student from completing the requirements for a regular high school diploma; and

(2) Not preclude a student with the most significant cognitive disabilities who takes an alternate assessment aligned with alternate academic achievement standards from attempting to complete the requirements for a regular high school diploma.

(e) *Inform parents.* A State (or in the case of a district-wide assessment, an LEA) must ensure that parents of students selected to be assessed using an alternate assessment aligned with alternate academic achievement standards under the State's guidelines in paragraph (c)(1) of this section are informed, consistent with 34 CFR 200.2(e), that their child's achievement will be measured based on alternate academic achievement standards, and of how participation in such assessments may delay or otherwise affect the student from completing the requirements for a regular high school diploma.

(f) *Reports.* An SEA (or, in the case of a district-wide assessment, an LEA) must make available to the public, and report to the public with the same frequency and in the same detail as it reports on the assessment of nondisabled children, the following:

(1) The number of children with disabilities participating in regular assessments, and the number of those children who were provided accommodations (that did not result in an invalid score) in order to participate in those assessments.

(2) The number of children with disabilities, if any, participating in alternate assessments based on grade-level academic achievement standards in school years prior to 2017–2018.

(3) The number of children with disabilities, if any, participating in alternate assessments aligned with modified academic achievement standards in school years prior to 2016–2017.

(4) The number of children with disabilities who are students with the most significant cognitive disabilities participating in alternate assessments aligned with alternate academic achievement standards.

(5) Compared with the achievement of all children, including children with disabilities, the performance results of children with disabilities on regular

assessments, alternate assessments based on grade-level academic achievement standards (prior to 2017–2018), alternate assessments based on modified academic achievement standards (prior to 2016–2017), and alternate assessments aligned with alternate academic achievement standards if—

(i) The number of children participating in those assessments is sufficient to yield statistically reliable information; and

(ii) Reporting that information will not reveal personally identifiable information about an individual student on those assessments.

* * * * *

§ 300.207 [Amended]

■ 17. Section 300.207 is amended by removing ''section 2122 of the ESEA'' and adding in its place ''section 2102(b) of the ESEA''.

§ 300.306 [Amended]

■ 18. Section 300.306 is amended in paragraph (b)(1)(i) by adding the phrase ''as such section was in effect on the day before the date of enactment of the Every Student Succeeds Act (December 9, 2015)'' after ''ESEA''.

§ 300.324 [Amended]

■ 19. Section 300.324 is amended in paragraph (d)(2)(ii) by removing ''300.112'' and adding in its place ''300.114''.

■ 20. Section 300.704 is amended:

■ A. In paragraph (b)(4)(x) by removing ''6111 of the ESEA'' and adding in its place ''1201 of the ESEA''.

■ B. Revising paragraph (b)(4)(xi).

■ C. In paragraph (c)(3)(i)(A)(*2*) by removing ''section 9101'' and adding in its place ''section 8101''.

The revision reads as follows:

§ 300.704 State-level activities.

* * * * *

(b) * * *

(4) * * *

(xi) To provide technical assistance to schools and LEAs, and direct services, including direct student services described in section 1003A(c)(3) of the ESEA, to children with disabilities, in schools or LEAs implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA on the basis of consistent underperformance of the disaggregated subgroup of children with disabilities, including providing professional development to special and regular education teachers who teach children with disabilities, based on scientifically based research to improve educational instruction, in order to improve academic achievement based on the challenging academic standards described in section 1111(b)(1) of the ESEA.

* * * * *

PART 303—EARLY INTERVENTION PROGRAM FOR INFANTS AND TODDLERS WITH DISABILITIES

■ 21. The authority citation for part 303 continues to read as follows:

Authority: 20 U.S.C. 1431 through 1444, unless otherwise noted.

§ 303.32 [Removed and Reserved]

■ 22. Remove and reserve § 303.32.

[FR Doc. 2017–13801 Filed 6–29–17; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 22, 85, 86, 600, 1033, 1036, 1037, 1039, 1042, 1043, 1065, 1066, and 1068

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 523, 534, 535, and 538

[EPA–HQ–OAR–2014–0827; NHTSA–2014–0132; FRL–9950–25–OAR]

RIN 2060–AS16; RIN 2127–AL52

Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles—Phase 2

Correction

■ In rule document 2016–21203, appearing on pages 73478–74274, in the issue of Tuesday, October 25, 2016, make the following corrections:

§ 1036.805 Symbols, abbreviations, and acronyms. [Corrected]

■ 1. On page 74044, in paragraph (b), the table should read as follows:

Symbol	Quantity	Unit	Unit symbol	Unit in terms of SI base units
a	atomic hydrogen-to-carbon ratio	mole per mole	mol/mol	1.
b	atomic oxygen-to-carbon ratio	mole per mole	mol/mol	1.
C_dA	drag area	meter squared	m^2	m^2.
C_{rr}	coefficient of rolling resistance	kilogram per metric ton	kg/tonne	10^{-3}.
D	distance	miles or meters	mi or m	m.
e	mass weighted emission result	grams/ton-mile	g/ton-mi	g/kg-km.
Eff	efficiency.			
E_m	mass-specific net energy content	megajoules/kilogram	MJ/kg	$m^2 \cdot s^{-2}$.
f_n	angular speed (shaft)	revolutions per minute	r/min	$\pi \cdot 30 \cdot s^{-1}$.
i	indexing variable.			
k_a	drive axle ratio.			
$k_{topgear}$	highest available transmission gear.			
m	mass	pound mass or kilogram	lbm or kg	kg.
M	molar mass	gram per mole	g/mol	$10^{-3} \cdot kg \cdot mol^{-1}$.
M	vehicle mass	kilogram	kg	kg.
$M_{rotating}$	inertial mass of rotating components	kilogram	kg	kg.
N	total number in a series.			
P	power	kilowatt	kW	$10^3 \cdot m^2 \cdot kg \cdot s^{-3}$.
T	torque (moment of force)	newton meter	N·m	$m^2 \cdot kg \cdot s^{-2}$.
t	time	second	s	s.
Δt	time interval, period, 1/frequency	second	s	s.
UF	utility factor.			
v	speed	miles per hour or meters per second	mi/hr or m/s	$m \cdot s^{-1}$.

Symbol	Quantity	Unit	Unit symbol	Unit in terms of SI base units
W	work	kilowatt-hour	kW·hr	$3.6 \cdot m^2 \cdot kg \cdot s^{-1}$.
w_C	carbon mass fraction	gram/gram	g/g	1.
w_{CH4N2O}	urea mass fraction	gram/gram	g/g	1.
x	amount of substance mole fraction	mole per mole	mol/mol	1.
x_b	brake energy fraction.			
x_{bl}	brake energy limit.			

§ 1037.550 Powertrain testing. [Corrected]

■ 2. On page 74097, in the third column, TABLE 1 OF § 1037.550—STATISTICAL CRITERIA FOR VALIDATING DUTY CYCLES should read as follows:

TABLE 1 OF § 1037.550—STATISTICAL CRITERIA FOR VALIDATING DUTY CYCLES

Parameter [1]	Speed control
Slope, a_1	$0.990 \leq a_1 \leq 1.010$.
Absolute value of intercept, $\|a_0\|$.	≤2.0% of maximum test speed.
Standard error of estimate, *SEE*.	≤2.0% of maximum test speed.
Coefficient of determination, r^2.	≥0.990.

[1] Determine values for specified parameters as described in 40 CFR 1065.514(e) by comparing measured and reference values for $f_{nref,dyno}$.

[FR Doc. C1–2016–21203 Filed 6–29–17; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0409; FRL–9955–67–Region 9]

Approval of California Air Plan Revisions, Great Basin Unified Air Pollution Control District and the Town of Mammoth Lakes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Great Basin Unified Air Pollution Control District (GBUAPCD) and the Town of Mammoth Lakes portion of the California State Implementation Plan (SIP). These revisions concern emissions of particulate matter (PM) from wood burning devices and road dust in the Town of Mammoth Lakes. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on August 29, 2017 without further notice, unless the EPA receives adverse comments by July 31, 2017. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0409 at *http://www.regulations.gov,* or via email to Andrew Steckel, Rulemaking Office Chief at *Steckel.Andrew@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov.* For either manner of submission, 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, (415) 947–4125, *vineyard.christine@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this action with the dates that they were adopted by the local agencies and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Revised	Submitted
GBUAPCD	431	Particulate Matter (except paragraphs M and N)	05/05/14	11/06/14
Town of Mammoth Lakes	8.30	Particulate Emissions Regulations (except paragraphs 8.30.110 and 8.30.120).	06/04/14	11/06/14

On December 11, 2014, the EPA determined that the submittal for GBUAPCD Rule 431 and Town of Mammoth Lakes Municipal Code Chapter 8.30 met the completeness criteria in 40 CFR part 51 Appendix V,

which must be met before formal EPA review.

B. Are there other versions of these rules?

We approved earlier versions of Rule 431 and Municipal Code Chapter 8.30 into the SIP on October 31, 2007 (72 FR 61526) and June 24, 1996 (61 FR 32341), respectively. The GBUAPCD and Town of Mammoth Lakes adopted revisions to the SIP-approved rules on May 5, 2014 and May 7, 2014 respectively, and CARB submitted them to us on November 6, 2014.

C. What is the purpose of the submitted rules?

PM, including PM equal to or less than 10 microns in diameter (PM_{10}), contributes to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires states to submit regulations that control PM emissions. GBUAPCD Rule 431 (except paragraphs M and N) and Town of Mammoth Lakes Municipal Code Chapter 8.30 (except paragraphs 8.30.110 and 8.30.120) were revised to be consistent with each other, and to enable the GBUAPCD to be able to enforce air quality regulations governing residential wood combustion and road dust in the Town of Mammoth Lakes.[1] The EPA's technical support document (TSD) has more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

SIP rules 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).

On October 5, 2015 (80 FR 60049), the EPA redesignated the Mammoth Lakes Planning Area to attainment of the 24-hour PM_{10} National Ambient Air Quality Standard, pursuant to CAA section 107(d)(3)(D), and determined that the area met the requirements of CAA section 107(d)(3)(E). Accordingly, the Mammoth Lakes Planning Area is not subject to the nonattainment area requirement to implement either Reasonably Available Control Measures (RACM) or Best Available Control Measures (BACM) for PM_{10} and PM_{10} precursors in CAA section 189(b) and (e). Therefore, we are not evaluating GBUAPCD Rule 431 and Mammoth Lakes Municipal Code Chapter 8.30 for compliance with current RACM or BACM requirements with respect to PM_{10}. Should a GBUAPCD nonattainment area take credit for Rule 431 in the future as part of meeting its CAA Part D requirements, then we will evaluate the rule for current RACM or BACM, as applicable, at that time.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' (57 FR 13498, April 16, 1992 and 57 FR 18070, April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' (''the Bluebook,'' U.S. EPA, May 25, 1988; revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' (''the Little Bluebook'', EPA Region 9, August 21, 2001).
4. ''PM_{10} Guideline Document,'' (EPA 452/R–93–008, April 1993).

B. Do the rules meet the evaluation criteria?

We believe these rules are consistent with the relevant policy and guidance regarding enforceability and SIP relaxations. The District is not including for SIP approval Rule 431 paragraphs M and N regarding fees and penalties, and similar provisions in Municipal Code Chapter 8.30, paragraphs 8.30.110 and 8.30.120. These paragraphs could lead to confusion with respect to similar federal requirements. The TSD has more information on our evaluation.

C. The EPA's Recommendations To Further Improve the Rules

The TSD describes additional rule revisions that we recommend for the next time the local agencies modify the rules.

D. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, the EPA is fully approving the submitted rules because we believe they fulfill all relevant requirements.[2] We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by July 31, 2017, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on August 29, 2017. This will incorporate these rules into the federally enforceable SIP.

Please note that if the EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the GBUAPCD Rule 431 (except paragraphs M and N) and Town of Mammoth Lakes Chapter 8.30 (except paragraphs 8.30.110 and 8.30.120), described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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 action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those

[1] Rule 431 may apply to communities other than the Town of Mammoth Lakes within the Great Basin Unified Air Quality Control District if a community is designated a High Wood Smoke Area according to the procedures set forth in the Rule.

[2] Upon the effective date of this final action, GBUAPCD Rule 431 (except paragraphs M and N) and Town of Mammoth Lakes Municipal Code Chapter 8.30 (except paragraphs 8.30.110 and 8.30.120) would supersede existing GBUAPD 431 and Town of Mammoth Lakes 8.30, approved at 72 FR 61526 on October 31, 2007 and 61 FR 32341 on June 24, 1996, respectively in the applicable SIP.

imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 29, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: November 14, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(228)(i)(A)(*1*)(*iii*), (c)(350)(i)(A)(*3*), and (c)(457)(i)(I) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(228) * * *

(i) * * *

(A) * * *

(*1*) * * *

(*iii*) Previously approved on October 2, 1991 in paragraph (c)(228)(i)(A)(*1*)(*ii*) of this section and now deleted with replacement in paragraph (c)(457)(i)(I)(*2*) of this section, Town of Mammoth Lakes Municipal Code Chapter 8.30 dated October 2, 1991.

* * * * *

(350) * * *

(i) * * *

(A) * * *

(*3*) Previously approved on October 31, 2007 in paragraph (c)(350)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(457)(i)(I)(*2*) of this section, Rule 431, adopted on December 7, 1990 and revised on December 4, 2006.

* * * * *

(457) * * *

(i) * * *

(I) Great Basin Unified Air Pollution Control District.

(*1*) Rule 431, Particulate Emissions (except paragraphs M and N), revised May 5, 2014.

(*2*) Town of Mammoth Lakes Municipal Code Chapter 8.30, Particulate Emissions Regulations (except paragraphs 8.30.110 and 8.30.120), as adopted in Ordinance Number 14–06, June 4, 2014.

* * * * *

Editorial note: This document was received for publication by the Office of the Federal Register on June 20, 2017.

[FR Doc. 2017–13196 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0011; FRL–9963–95–Region 8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Mystery Bridge Road/ U.S. Highway 20 Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 8 is publishing a direct final notice of Partial Deletion of the property currently owned by Tallgrass Energy Partners, LP, (formerly owned by KM Upstream LLC and hereinafter referred to as the former KMI

Property), on the Mystery Bridge Road/U.S. Highway 20 Site (Site) from the National Priorities List (NPL). The Site is located in Natrona County, northeast of Casper, Wyoming. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution and Contingency Plan (NCP). This direct final partial deletion is being published by EPA with the concurrence of the State of Wyoming through the Wyoming Department of Environmental Quality (WDEQ) because EPA has determined that all appropriate response actions under CERCLA, other than maintenance of institutional controls and five-year reviews, have been completed for the former KMI source area and the resultant groundwater contamination. However, this deletion does not preclude future actions under Superfund.

This partial deletion pertains to the former KMI Property. EPA is proposing to delete the entire former KMI Property from the NPL, including the groundwater (OU1) and the soil/former source area (OU2). The remaining areas and media of the Site for both OU1 and OU2 containing the volatile halogenated organic chemicals (VHOs) source soils and plume, which are attributable to the Dow Chemical Company/Dowell Schlumberger, Inc. (DOW/DSI) facility, will remain on the NPL and are not being considered for deletion as part of this action. However, this partial deletion does not preclude future actions under Superfund.

DATES: This direct final rule is effective August 29, 2017 unless EPA receives adverse comments by July 31, 2017. If adverse comments are received, EPA will publish a timely withdrawal of the direct final partial deletion in the **Federal Register** informing the public that the partial deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1990–0011, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments.
- *Email:* Andrew Schmidt (*schmidt.andrew@epa.gov*).
- *Mail:* Andrew Schmidt, Remedial Project Manager, 8EPR–SR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202.
- *Hand Delivery:* Andrew Schmidt, Remedial Project Manager, 8EPR–SR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1990–0011. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The Web site, *http://www.regulations.gov,* is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at: U.S. EPA Region 8, Superfund Records Center & Technical Library, 1595 Wynkoop Street, Denver, CO 80202–1129.

Viewing hours: 8 a.m. to 4:00 p.m., Monday through Thursday, excluding holidays;

Contact: Andrew Schmidt; (303) 312–6283; email: *schmidt.andrew@epa.gov* and Natrona County Public Library, Reference Desk, 307 East 2nd Street, Casper, WY 82601–2593, (307) 237–4935.

Monday–Thursday: 9 a.m.–6 p.m.
Friday and Saturday: 9 a.m.–5 p.m.

FOR FURTHER INFORMATION CONTACT: Andrew Schmidt, Remedial Project Manager, 8EPR–SR, U.S. Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129, (303) 312–6283, email: *schmidt.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 8 is publishing this direct final notice of Partial Deletion for the former KMI Property of the Mystery Bridge Road/U.S. Highway 20 Superfund Site (Site) from the National Priorities List (NPL). The former KMI Property includes areas of soil and groundwater formerly impacted by benzene, toluene, ethylbenzene, and total xylenes (collectively known as BTEX) contamination. A map and surveyed boundaries of the former KMI Property are included in the docket and at the information repositories listed above. The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This partial deletion of the Mystery Bridge Road/U.S. Highway 20 Superfund Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the NPL, 60 FR 55466 (Nov. 1, 1995). As described in § 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

Because EPA considers this action to be non-controversial and routine, this action will be effective August 29, 2017 unless EPA receives adverse comments

by July 31, 2017. Along with this direct final Notice of Partial Deletion, EPA is co-publishing a Notice of Intent for Partial Deletion in the ''Proposed Rules'' section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this partial deletion action, EPA will publish a timely withdrawal of this direct final Notice of Partial Deletion before the effective date of the partial deletion, and the partial deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Partial Deletion and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Mystery Bridge Road/U.S. Highway 20 Superfund Site and demonstrates how portions of the Site proposed for deletion meet the deletion criteria. Section V discusses EPA's action to partially delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR Section 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed responses under CERCLA have been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Partial Deletion Procedures

The following procedures apply to the deletion of the former KMI Property of the Site:

1. EPA has consulted with the State of Wyoming prior to developing this direct final Notice of Partial Deletion and the Notice of Intent for Partial Deletion co-published in the ''Proposed Rules'' section of the **Federal Register**.

2. EPA has provided the State 30 working days for review of this notice and the parallel Notice of Intent for Partial Deletion prior to their publication today. The State, through the Wyoming Department of Environmental Quality (WDEQ), has concurred on the partial deletion of the Site from the NPL.

3. Concurrent with the publication of this direct final Notice of Partial Deletion, a notice of the availability of the parallel Notice of Intent for Partial Deletion is being published in a major local newspaper, the Casper Star Tribune. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

4. The EPA placed copies of documents supporting the partial deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

5. If adverse comments are received within the 30-day public comment period on this partial deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Partial Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent for Partial Deletion and the comments already received.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for further response actions, should future conditions warrant such actions.

IV. Basis for Partial Site Deletion

The following information provides EPA's rationale for deleting the former KMI Property from the Mystery Bridge Road/U.S. Highway 20 Superfund Site.

Site Background and History

The Mystery Bridge Road/U.S. Highway 20 Superfund Site (Site), EPA ID No. WYD981546005, is located in Natrona County, Wyoming northeast of Casper, Wyoming and one mile east of Evansville. The Site is bordered on the north by the North Platte River, on the west by the Sinclair Refinery (formerly known as the Little America Refining Company or LARCO), on the south by U.S. Highway 20 and on the east by Mystery Bridge Road. The northern two thirds of the Site contain residential housing units built primarily between 1973 and 1983. The former KN Energy (KN) facility, now owned by Tallgrass Energy Partners, LP, formerly owned by KM Upstream LLC and referred to in this Notice of Partial Deletion as the former KMI Property, and the adjacent Dow Chemical Company and Dowell-Schlumberger, Inc (DOW/DSI) facilities comprise the southern third of the Site. Site investigations, initiated due to resident complaints of poor water and air quality, were completed in 1986 and 1987 and identified a BTEX plume originating from the former KMI Property and a volatile halogenated organic chemicals (VHOs) plume originating from the DOW/DSI property, moving northeast towards the North Platte River. The Site was proposed for listing on the National Priorities List June 24, 1988 (53 FR 23996, 23749–24010 (June 24, 1988)), and was listed on the National Priorities List on August 30, 1990 (55 FR 35508, 35419–35554 (August 30, 1990)). Potential releases at the Sinclair Refinery (formerly LARCO) facility are currently being addressed under a RCRA 3008(h) order.

KM Upstream LLC and its predecessors have operated a natural gas fractionation, compression, cleaning, odorizing, and transmission plant at the Site since 1965. During the plant start-up, an underground pipe burst, injecting 5,000 to 10,000 gallons of absorption oil into the subsurface. Also, initially, an earthen flare pit was used to collect spent material generated by the facility. Absorption oil, emulsions, anti-foulants, and anti-corrosive agents, crude oil condensate, liquids accumulated in the flare stack, potassium hydroxide treated waste, and lubrication oils and blowdown materials from plant equipment were all possibly collected in

the flare pit. In 1984, a concrete-lined flare pit was constructed and put into operation. Leaks from the earthen flare pit, the initial absorption oil spill, and a catchment area that collected surface water run-off are all believed to have contributed to the BTEX soil and groundwater impacts.

The DOW/DSI facility has conducted oil and gas production enhancement services for the oil and gas industry since the 1950's. Contamination originating from the DOW/DSI facility is believed to have come from the truck wash water disposal system (believed to have contained chlorinated solvents) and the toluene storage area on the northern end of the facility.

EPA is the lead agency for the Site, and WDEQ is the support agency. Pursuant to the 1991 Consent Decree, KN, its successor Kinder Morgan Inc. (KMI), and DOW/DSI have jointly conducted and funded the remediation work at the Site. The former KMI Property is in continued operation as mid-stream gas processing facility.

The Site was divided into two media-specific operable units (OUs). OU1 refers to the groundwater at the Site and OU2 refers to the source areas in the soil at the Site.

Remedial Investigations and Feasibility Study (RI/FS) and Engineering Evaluations/Cost Analysis (EE/CA)

Numerous studies and remedial investigations conducted within the Site have addressed the former KMI Property. In December 1987, KN and DOW/DSI entered into Administrative Orders on Consent (AOCs) to perform removal actions at their respective facilities. Based on the findings of the initial investigation, each PRP was required to prepare an Engineering Evaluation/Cost Analysis (EE/CA) of its property to document the extent and nature of the contaminants present and to support proposals of expedited removal actions. The AOC also required the two PRPs to perform a Remedial Investigation/Feasibility Study (RI/FS) of the Brookhurst Subdivision site. The Mystery Bridge/U.S. Hwy 20 Superfund site includes the former KMI Property, the DOW/DSI property, several adjacent industrial properties, the Burlington Northern right-of-way and the Subdivision. The Brookhurst Subdivision RI/FS was submitted in June 1990 and concluded that two groundwater plumes originated from the industrial area, one from the DOW/DSI property containing VHOs and one from the former KMI Property contaminated with BTEX and suggested that the two plumes were not commingled.

In early 1988, Phase I and Phase II Environmental Site Assessments were performed on the former KMI Property, focusing on the area around the flare pit. Based on the free product findings, a Phase III Environmental Site Assessment, including a soil vapor survey, was conducted in mid-1988 to identify the extent of impacts. The EPA developed site-specific soil action levels (SALs) in 1988 for the former KMI Property that were based on toxicity data current at the time including:

- Benzene: 80 to 82 micrograms per kilogram (µg/kg)
- Ethylbenzene: 182,000 to 325,000 µg/kg
- Toluene: 71,000 to 107,000 µg/kg
- Total Xylenes: 176,000 µg/kg

In March 1989, the KN EE/CA was submitted to the EPA.

Selected Remedy

On July 14, 1989 the EPA signed an action memorandum, choosing the suggested response strategy outlined by the EE/CA. In November 1989, KN started the OU1 response actions, coupling a groundwater pump and treat system with a soil vapor extraction system, to remove BTEX contaminants in three phases: Soil vapor, floating product, and dissolved in groundwater. In September 1990, EPA issued a Record of Decision (ROD) dividing the Site into two operable units: OU1, groundwater contaminant plumes, and OU2, contaminated soils which represent a source for the groundwater contamination. The 1990 ROD selected a remedial action for OU1, the groundwater, and deferred selection of the remedial action for OU2. The OU1 ROD set out the following remedial action objectives (RAOs) for the BTEX contamination:

(1) Prevent ingestion of water containing benzene, toluene, ethylbenzene, or xylene at concentrations that either (a) exceed MCLs or proposed MCLs, or (b) Present a total carcinogenic risk range greater than 1×10^{-4} to 1×10^{-6}; and

(2) Restore the alluvial aquifer to concentrations that both (a) meet the MCLs or proposed MCLs for benzene, toluene, ethylbezene, and xylene, and (b) Present a total carcinogenic risk range less than 1×10^{-4} to 1×10^{-6}. The area of attainment included the entire BTEX groundwater plume.

The applicable MCLs for BTEX were the National Primary Drinking Water Regulations (40 CFR 141.61):

- Benzene: 0.005 milligrams per liter (mg/L)
- Ethylbenzene: 0.7 mg/L
- Toluene: 1 mg/L
- Total Xylenes 10 mg/L

An institutional control to restrict the groundwater use was also included in the OU1 ROD. In October 1991, a Consent Decree, where parties agreed to implement the OU1 remedy, was signed between EPA, KN and DOW/DSI.

Response Actions

The KN OU1 remediation system operated from November 1989 to August 1996 and involved a pump-and-treat system, where the effluent was sent through an air stripper and a soil vapor extraction system. The clean effluent from the air stripper was returned to the subsurface. A groundwater monitoring plan (GWP) was developed in 1993 and specified that quarterly post-remedial action (RA) monitoring would begin after the remediation system was discontinued and 12 months of groundwater sampling results were below the MCLs.

KMI assumed responsibility for KN's portion of the Site when KMI purchased KN in 1999. After a minimum of eight quarterly post-RA sampling events were conducted where the 90 percent one-tailed upper confidence limit (UCL90) concentrations for benzene, ethylbenzene, toluene, and total xylenes were below the MCLs for each chemical, compliance with the RAOs for the BTEX groundwater plume was achieved. It was confirmed that the OU1 RAOs were achieved in 2010 and the results were recorded in the September 30, 2010 OU2 ROD.

KN, KMI, and DOW each conducted work at the Site under an Administrative Order on Consent that addressed the contaminated soils on their respective properties. The OU2 ROD served to document that this previous work was completed and that this work cleaned up the DOW/DSI property and the KMI Property to levels safe for industrial use. Contaminants have been left above levels that allow for unlimited use and unrestricted exposure and it is acknowledged that land uses around these properties are transitioning from rural to residential and commercial. The OU2 ROD concluded that ICs were necessary for future protectiveness. Specifically for the former KMI Property, the RAOs specified in the OU2 ROD include:

- Restricting the use of the KMI Property to industrial uses.
- Controlling the handling of excavated soils on the KMI Property.

The OU2 RAOs have been achieved through institutional controls placed on the former KMI Property and implemented through restrictive covenants within the deed transferring the KMI Property from KMI to KM

Upstream LLC and, more recently, to Tallgrass Energy Partners, LP. The ground water institutional control from the OU1 ROD restricting ground water use except for sampling purposes at the former KMI Property was also implemented in 2010 as part of the restrictive covenants.

Operation and Maintenance

No operation and maintenance is required at the former KMI Property in addition to maintaining institutional controls.

Five-Year Review

Because the remedial action implemented for the former KMI Property results in contaminants remaining on site above concentrations that allow for unlimited use and unrestricted exposure, continued five-year reviews will be necessary to ensure that the remedy is protective of human health and the environment. The Fourth Five-Year Review for the Site, noted that the pump and treat remedy, as selected in the ROD, was shutdown prior to meeting cleanup levels at the site. Proper documentation for the shutdown, and Agency approval was identified for the decision to turn of the pump and treat system, and can be found in the deletion docket.

Community Involvement

Public participation activities have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k) and CERCLA section 117, 42 U.S.C. 9617. Documents in the partial deletion docket, which the EPA relied on for the partial deletion from the NPL, are available to the public in the information repositories, and a notice of availability of the Intent for Partial Deletion has been published in the Casper Star Tribune to satisfy public participation procedures required by 40 CFR 300.425(e)(4).

Determination That the Criteria for Deletion Have Been Met

For the former KMI Property of both OU1 and OU2, EPA and the WDEQ have determined that the responsible parties completed all appropriate response actions required by the OU1 and OU2 Records of Decision and the 1991 Consent Decree. Additionally, institutional controls are in place that will limit property use to industrial purposes only and will control the handling of excavated soils and restrict ground water use to sampling only without further approval from EPA or the State. EPA has consulted with the State on the proposed partial deletion of the former KMI Property from OU1 and OU2 from the NPL prior to developing this notice of Partial Deletion.

Pursuant to CERCLA section 121(c) and the NCP, EPA will conduct the next five-year review by September 2019 to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure.

V. Partial Deletion Action

The EPA, with the concurrence of the State of Wyoming through WDEQ, has determined that all appropriate response actions under CERCLA, other than maintenance of institutional controls and five-year reviews, have been completed. Therefore, EPA is deleting the former KMI Property, including the groundwater from OU1 and the soils/source area from OU2 of the Mystery Bridge Road/U.S. Highway 20 Superfund Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective August 29, 2017 unless EPA receives adverse comments by July 31, 2017. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of partial deletion before the effective date of the partial deletion and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to partially delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: May 1, 2017.

Debra H. Thomas,

Acting Regional Administrator, U.S. Environmental Protection Agency, Region 8.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by revising the entry under ''WY,'' ''Mystery Bridge Road/U.S. Highway 20,'' ''Evansville'' to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes (a)
*	*	*	*
WY	Mystery Bridge Road/U.S. Highway 20	Evansville/Natrona	P

(a) = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).
P = Sites with partial deletion(s).

* * * * *

[FR Doc. 2017–13678 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[GN Docket No. 12–268, WT Docket Nos. 14–70, 05–211, RM–11395; FCC 15–80]

Updating Competitive Bidding Rules

AGENCY: Federal Communications Commission.

ACTION: Announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved the information collection requirements associated with the FCC 15–80, Updating Part 1 Competitive Bidding Rules, published on September 18, 2015. This document is consistent with FCC 15–80, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of changes to the forms.

DATES: FCC 15–80 and the changes to FCC Form 603 and FCC Form 608 published at 80 FR 56764 will become effective on June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that on June 8, 2017, OMB approved the information collection requirements, OMB Control Numbers 3060–0800 and 3060–1058, for changes to the FCC Forms 603 and 608.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that on June 8, 2017, OMB approved changes to FCC Form 603 and FCC Form 608. In doing so, OMB approved changes to the information collection requirements of OMB Control Numbers 3060–0800 and 3060–1058. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Numbers are 3060–0800 and 3060–1058.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0800.

OMB Approval Date: June 8, 2017.

OMB Expiration Date: June 30, 2020.

Title: FCC Application for Assignments of Authorization and Transfers of Control: Wireless Telecommunications Bureau and/or Public Safety and Homeland Security Bureau.

Form Number: FCC Forms 603.

Respondents: Individuals and households; Business or other for-profit entities; Not-for-profit institutions; and State, local or tribal government.

Number of Respondents and Responses: 2,447 respondents and 2,447 responses.

Estimated Time per Response: 0.5–1.75 hours.

Frequency of Response: Recordkeeping requirement, on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 154, 155, 158, 161, 301, 303(r), 308, 309, 310 and 332.

Total Annual Burden: 2,759 hours.

Total Annual Cost: $366,975.

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information.

Privacy Act Impact Assessment: Yes.

Needs and Uses: FCC Form 603 is a multi-purpose form used to apply for approval of assignment or transfer of control of licenses in the wireless services. The data collected on this form is used by the FCC to determine whether the public interest would be served by approval of the requested assignment or transfer. This form is also used to notify the Commission of consummated assignments and transfers of wireless and/or public safety licenses that have previously been consented to by the Commission or for which notification but not prior consent is required. This form is used by applicants/licensees in the Advanced Wireless Services, Public Mobile Services, Personal Communications Services, General Wireless Communications Services, Private Land Mobile Radio Services, Broadcast Auxiliary Services, Broadband Radio Services, Educational Radio Services, Fixed Microwave Services, Maritime Services (excluding ships), and Aviation Services (excluding aircraft).

The purpose of this form is to obtain information sufficient to identify the parties to the proposed assignment or transfer, establish the parties' basic eligibility and qualifications, classify the filing, and determine the nature of the proposed service. Various technical schedules are required along with the main form applicable to Auctioned Services, Partitioning and Disaggregation, Undefined Geographical Area Partitioning, Notification of Consummation or Request for Extension of Time for Consummation.

The data collected on FCC Form 603 includes the FCC Registration Number (FRN), which serves as a ''common link'' for all filings an entity has with the FCC. The Debt Collection Improvement Act of 1996 requires entities filing with the Commission use an FRN.

The OMB approved revisions to the previously approved collection of information under OMB Control Number 3060–0800 to permit the collection of the additional information for Commission licenses and permits, pursuant to the rules and information collection requirements adopted by the Commission in the Part 1 R&O and the Mobile Spectrum Holdings R&O. As part of the collection, the Commission is seeking approval for the information collection and recordkeeping requirements associated with FCC Form 603.

In addition, OMB approved various other, non-substantive editorial/consistency edits and updates to FCC Form 603 that corrected inconsistent capitalization of words and other typographical errors, and better align the text on the form with the text in the Commission rules both generally and in connection with recent non-substantive, organizational amendments to the Commission's rules. Also, in certain circumstances, the Commission requires the applicant to provide copies of their agreements. The Commission did not anticipate that these revisions will impact the collection filing burden. OMB therefore approved the FCC revision of its currently approved information collection on FCC Form 603 to revise FCC Form 603 accordingly.

OMB Control Number: 3060–1058.

OMB Approval Date: June 8, 2017.

OMB Expiration Date: June 30, 2020.

Title: FCC Application or Notification for Spectrum Leasing Arrangement: Wireless Telecommunications Bureau and/or Public Safety and Homeland Security Bureau.

Form Number: FCC Form 608.

Respondents: Business or other for profit entities; Not-for-profit institutions; and State, local or tribal government.

Number of Respondents and Responses: 991 respondents; 991 responses.

Estimated Time per Response: 0.5–1 hours.

Frequency of Response: Recordkeeping requirement, on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. 154, 155, 158, 161, 301, 303(r), 308, 309, 310 and 332.

Total Annual Burden: 996 hours.

Total Annual Cost: $1,282,075.

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: FCC Form 608 is a multipurpose form. It is used to provide notification or request approval for any spectrum leasing arrangement (''Leases'') entered into between an existing licensee (''Licensee'') in certain wireless services and a spectrum lessee (''Lessee''). This form also is required to notify or request approval for any spectrum subleasing arrangement (''Sublease''). The data collected on the form is used by the FCC to determine whether the public interest would be served by the Lease or Sublease. The form is also used to provide notification for any Private Commons Arrangement entered into between a Licensee, Lessee, or Sublessee and a class of third-party users (as defined in Section 1.9080 of the Commission's Rules).

The OMB approved revisions to the previously approved collection of information under OMB Control Number 3060–1058 to permit the collection of the additional information for Commission licenses and permits, pursuant to the rules and information collection requirements adopted by the Commission in the Part 1 R&O and the Mobile Spectrum Holdings R&O. As part of the collection, the Commission is seeking approval for the information collection and recordkeeping requirements associated with FCC Form 608.

In addition, OMB approved various other, non-substantive editorial/consistency edits and updates to FCC Form 608 that corrected inconsistent capitalization of words and other typographical errors, and better align the text on the form with the text in the Commission rules both generally and in connection with recent non-substantive, organizational amendments to the Commission's rules. Also, in certain circumstances, the Commission requires the applicant to provide copies of their agreements. The Commission did not anticipate that these revisions will impact the collection filing burden. OMB therefore approved the FCC revision of its currently approved information collection on FCC Form 608 to revise FCC Form 608 accordingly.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2017–12954 Filed 6–29–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 16–306, GN Docket No. 12–268; DA 17–484]

Transition Progress Report Form and Filing Requirements for Stations Not Eligible for Reimbursement From the TV Broadcast Relocation Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) describes the information that must be provided in periodic progress reports (FCC Form 2100—Schedule 387 (Transition Progress Report)) by full power and Class A television stations that are not eligible to receive payment of relocation expenses from the TV Broadcast Relocation Fund in connection with their being assigned to a new channel through the Incentive Auction.

DATES: Effective June 30, 2017.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, *Joyce.Bernstein@fcc.gov,* (202) 418–1647, or Kevin Harding, *Kevin.Harding@fcc.gov,* (202) 418–7077.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, DA 17–484, MB Docket No. 16–306, GN Docket No. 12–268, adopted and released May 18, 2017. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text of this document is also available for download at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2017/db0518/DA-17-484A1.pdf.*

Synopsis

The Incentive Auction Task Force and Media Bureau (collectively, the Commission) previously determined that stations that are eligible for reimbursement from the TV Broadcast Relocation Fund in connection with their being assigned to a new channel through the Incentive Auction must file reports showing how the disbursed funds have been spent and what portion of the stations' construction in complete, and sought comment on whether non-reimbursable stations should also file reports to show what portion of the stations' construction is complete. These Transition Progress Reports will help the Commission, broadcasters, those involved in construction of broadcast facilities, other interested parties, and the public to monitor the construction of stations.

The Commission announces that each full power and Class A television station that will be changing channels during the post-incentive auction transition and is not eligible for reimbursement of its relocation costs from the TV Broadcast Relocation Fund established by the Middle Class Tax Relief and Job Creation Act of 2012 must follow the same progress reporting requirements as reimbursable stations and periodically file an FCC Form 2100—Schedule 387 (Transition Progress Report) that is attached as Appendix A to the Public Notice DA 17–34. The appendix is available at *https://apps.fcc.gov/edocs_public/attachmatch/DA-17-34A1.docx.* Non-Reimbursable stations must file Transition Progress Reports using the Commission's electronic filing system starting with first full calendar quarter after close of the Incentive Auction, which occurred on April 13, 2017, and on a quarterly basis thereafter. In addition to these quarterly reports, Non-Reimbursable stations must file the reports: (1) 10 weeks before the end of their assigned construction deadline; (2) 10 days after they complete all work related to construction of their post-auction facilities; and (3) five days after they cease broadcasting on their pre-auction channel. Once a station has filed a Transition Progress Report certifying that it has completed all work related to construction of its post-auction facilities and has ceased operating on its pre-auction channel, it will no longer be required to file reports. The Commission will automatically line the Transition Progress Reports to non-reimbursable stations' online local public inspection file on the Commission's Web site.

Some commenters proposed changes to questions in the Transition Progress Report Form adopted for reimbursable stations and certain filing procedures, which the Commission treated as requests for reconsideration and declined to adopt. The Commission declined to incorporate the response of ''unknown at this time'' into the form for each question, to change the wording of a question dealing with auxiliary antenna systems, to require a more detailed level of reporting with respect to a number of questions, to require reports to be filed on a less frequent basis, or to allow group owners to file a single report for all of their stations.

Paperwork Reduction Act of 1995 Analysis: This document contains new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, has invited the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document in a separate **Federal Register** Notice, as required by the Paperwork Reduction Act of 1995, Public Law 104–13, see 44 U.S.C. 3507.

The Commission will send a copy of the document, DA 17–484, in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Appendix B: Final Regulatory Flexibility Act Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (''RFA''), an Initial Regulatory Flexibility Analysis (''IRFA'') was incorporated in the *Transition Progress Report Public Notice.* The Incentive Auction Task Force and Media Bureau sought written public comments on the proposals in the *Transition Progress Report Public Notice,* including comment on the IRFA. Because we adopt filing requirements for stations in the Public Notice, we have included this Final Regulatory Flexibility Analysis (''FRFA''), which conforms to the RFA.

Need for, and Objectives of, the Rule Changes. The Federal Communications Commission (Commission) adopted a 39-month transition period during which television stations that are assigned to new channels in the incentive auction must construct their new facilities. The Commission determined that reassigned television stations that are eligible for reimbursement from the TV Broadcast Relocation Fund are required, on a regular basis, to provide progress reports to the Commission showing how the disbursed funds have been spent and what portion of construction is complete. In the *Transition Progress Report Public Notice,* the Media Bureau adopted a form for such progress reports and set the filing deadlines for such reports. The Public Notice requires that that reassigned television stations that are not eligible for reimbursement from the TV Broadcast Relocation Fund (Non-Reimbursable Stations) provide the same progress reports to the Commission on the same schedule as that specified for stations eligible for reimbursement. The Transition Progress Report Form requires all reassigned stations to certify that certain steps toward construction of their post-auction channel either have been completed or are not required, and to identify potential problems which they believe may make it difficult for them to meet their construction deadlines. The information in the progress reports will be used by the Commission, stations, and other interested parties to monitor the status of reassigned stations' construction during the 39-month transition period.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA. No formal comments were filed on the IRFA.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration. No comments were filed on the IRFA by the Small Business Administration.

Description and Estimate of the Number of Small Entities to Which the Rules Will Apply. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

Television Broadcasting. This Economic Census category ''comprises establishments primarily engaged in broadcasting images together with sound.'' These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA has created the following small business size standard for such businesses: those having $38.5 million or less in annual receipts. The 2012 Economic Census reports that 751 firms in this category operated in that year. Of that number, 656 had annual receipts of $25,000,000 or less, 25 had annual receipts between $25,000,000 and $49,999,999 and 70 had annual receipts of $50,000,000 or more. Based on this data we therefore estimate that the majority of commercial television broadcasters are small entities under the applicable SBA size standard.

The Commission has estimated the number of licensed commercial television stations to be 1,384. Of this total, 1,264 stations (or about 91 percent) had revenues of $38.5 million or less, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) on February 24, 2017, and therefore these licensees qualify as small entities under the SBA definition. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 394. Notwithstanding, the Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

We note, however, that in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive to that extent.

Class A TV Stations. The same SBA definition that applies to television broadcast stations would apply to licensees of Class A television stations. As noted above, the SBA has created the following small business size standard

for this category: Those having $38.5 million or less in annual receipts. The Commission has estimated the number of licensed Class A television stations to be 417. Given the nature of these services, we will presume that these licensees qualify as small entities under the SBA definition.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements. The Public Notice adopted the following new reporting requirements. Non-Reimbursable Stations must file the Transition Progress Report on a quarterly basis, with the first Report being filed beginning for the first full quarter after the release of a public notice announcing the completion of the incentive auction. The deadline for filing the first Report is October 10, 2017. We further require that Non-Reimbursable Stations file Transition Progress Reports: (1) 10 weeks before the end of their assigned construction deadline; (2) 10 days after they complete all work related to construction of their post-auction facilities; and (3) five days after they cease broadcasting on their pre-auction channel. The Transition Progress Reports will be filed electronically using the Commission's electronic filing system, and the Commission will make the filings viewable in stations' online public inspection files. All reassigned stations are assigned to one of 10 Post-Auction Transition Plan Phase with construction deadline requirements ranging from November 30, 2018 to July 3, 2020. Once a station has ceased operating on its pre-auction channel, it no longer needs to file reports.

Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standard; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

The reporting requirement adopted in the Public Notice will allow the Commission, broadcasters (including those filing the Reports), and other interested parties to more closely monitor the status of construction during the transition, and focus resources on ensuring successful completion of the transition by all reassigned stations and continuity of over-the-air television service. In addition, the burdens of the reporting requirements are minimal and we believe the benefits of the reporting requirements, which will facilitate the successful post-incentive auction transition, outweigh any burdens associated with compliance.

Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rule. None.

Report to Congress. The Commission will send a copy of the Public Notice, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act. A copy (or summary thereof) will also be published in the **Federal Register**.

Report to Small Business Administration. The Commission will send a copy of the Public Notice, including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Thomas Horan,

Chief of Staff.

[FR Doc. 2017–13765 Filed 6–29–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 161020986–7352–02]

RIN 0648–BG38

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic Region; Amendment 36

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement Amendment 36 to the Fishery Management Plan (FMP) for the Snapper-Grouper Fishery of the South Atlantic Region as prepared and submitted by the South Atlantic Fishery Management Council (Council). This final rule modifies the FMP framework procedures to allow spawning special management zones (SMZs) to be established or modified through the framework process; establishes spawning SMZs off North Carolina, South Carolina, and Florida; establishes transit and anchoring provisions in the spawning SMZs; and establishes a sunset provision for most of the spawning SMZs. This final rule also moves the boundary of the existing Charleston Deep Artificial Reef Marine Protected Area (MPA). The purpose of this final rule is to protect spawning snapper-grouper species and the habitat where they spawn, and to reduce bycatch and bycatch mortality for snapper-grouper species, including speckled hind and warsaw grouper.

DATES: This final rule is effective July 31, 2017.

ADDRESSES: Electronic copies of Amendment 36 may be obtained from *www.regulations.gov* or the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.* Amendment 36 includes an environmental assessment, Regulatory Flexibility Act (RFA) analysis, regulatory impact review, and fishery impact statement.

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *frank.helies@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic region is managed under the FMP and includes speckled hind and warsaw grouper, along with other snapper-grouper species. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On January 4, 2017, NMFS published a notice of availability of Amendment 36 and requested public comment (82 FR 810). On January 18, 2017, NMFS published the proposed rule to implement Amendment 36 and requested public comment (82 FR 5512). The proposed rule and Amendment 36 outline the rationale for the actions contained in this final rule. A summary of the actions implemented by Amendment 36 and this final rule is provided below.

Management Measures Contained in This Final Rule

This final rule modifies the FMP framework procedures to allow spawning SMZs to be established or modified through the framework process; establishes spawning SMZs off North Carolina, South Carolina, and Florida; establishes transit and anchoring provisions in the spawning SMZs; establishes a sunset provision for

most of the spawning SMZs; and moves the existing Charleston Deep Artificial Reef MPA 1.4 mi (2.3 km) northwest to match the permitted site boundary.

Modify the FMP Framework Procedures for Spawning SMZs

The current FMP contains framework procedures to allow the Council to modify certain management measures, such as annual catch limits and other management measures, via an expedited process (see 50 CFR 622.194; 56 FR 56016, October 31, 1991). In Amendment 36 and this final rule, the Council has included changes to spawning SMZs, such as boundary modifications and the establishment or removal of spawning SMZs, under the framework process. For example, this final rule allows the Council to remove a spawning SMZ if monitoring efforts do not document evidence of spawning snapper-grouper species within the boundary. The revisions to the FMP framework procedures also allow the Council to remove the 10-year sunset provision for a spawning SMZ if monitoring efforts document snapper-grouper species' spawning inside a spawning SMZ. The Council decided that changing spawning SMZs through an expedited process can have beneficial biological and socio-economic impacts, especially if the changes respond to newer information, such as spawning locations for snapper-grouper species. The Council concluded that the framework process will allow adequate time for the public to comment on any proposed change related to a spawning SMZ.

Establish Spawning SMZs Off North Carolina, South Carolina, and Florida

The Council is establishing five snapper-grouper spawning SMZs in the South Atlantic off North Carolina, South Carolina, and Florida. This final rule prohibits fishing for or harvest of snapper-grouper species year-round in the spawning SMZs. The final rule establishes other restrictions in the spawning SMZs, including transiting with snapper-grouper species on board and anchoring.

The spawning SMZ off North Carolina is called South Cape Lookout (5.1 sq mi; 13.2 sq km). The final rule establishes three spawning SMZs off South Carolina that are called Devil's Hole/Georgetown Hole (3.03 sq mi; 7.8 sq km), Area 51 (approximately 3 sq mi; 7.8 sq km), and Area 53 (approximately 3 sq mi; 7.8 sq km). The spawning SMZ off the east coast of the Florida Keys is called Warsaw Hole/50 Fathom Hole (3.64 sq mi; 9.4 sq km).

Another purpose of spawning SMZs is to reduce bycatch and bycatch mortality of snapper-grouper species, including speckled hind and warsaw grouper. Currently, retention of speckled hind and warsaw grouper is prohibited in Federal waters in the South Atlantic. Prohibiting the targeting or harvest of snapper-grouper species in specified areas where these species are known to occur and possibly spawn is expected to reduce encounters with these deep-water species and provide protection for reproduction. The Council concluded that protecting snapper-grouper species within the spawning SMZs could enhance the opportunity for these species to reproduce and introduce more eggs and larvae into the environment.

Establish Transit and Anchoring Provisions in Spawning SMZs

This final rule allows fishing vessels to transit through the spawning SMZs with snapper-grouper species on board only when fishing gear is properly stowed. ''Properly stowed'' means that trawl or try nets and the attached doors must be out of the water, but are not be required to be on deck or secured below deck. Terminal gear (hook, leader, sinker, flasher, or bait) used with automatic reels, bandit gear, buoy gear, handline, or rod and reel would have to be disconnected and stowed separately from such fishing gear and sinkers would have to be disconnected from down riggers and stowed separately. Except under the limited condition to possess snapper-grouper species while transiting a spawning SMZ with fishing gear properly stowed, vessels in the spawning SMZs are prohibited from fishing for, harvesting, or possessing snapper-grouper species year-round in these areas. Except for the Area 51 and Area 53 Spawning SMZs off South Carolina, persons on board a fishing vessel are not allowed to anchor, use an anchor or chain, or use a grapple and chain while in spawning SMZs. Fishermen continue to be allowed to troll for pelagic species such as dolphin, tuna, and billfish in spawning SMZs.

Establish a Sunset Provision for Most Spawning SMZs

This final rule implements a 10-year sunset provision for the establishment of the spawning SMZs, except for the Area 51 and Area 53 Spawning SMZs, which will remain in effect indefinitely. Therefore, except for Areas 51 and 53, the spawning SMZs and their associated management measures are effective for 10 years following the implementation of this final rule for Amendment 36. For the spawning SMZs and management measures subject to the sunset provision to extend beyond 10 years, the Council would need to take further action. The Council will regularly evaluate all of the spawning SMZs over the 10-year period.

Move the Existing Charleston Deep Artificial Reef MPA

This final rule moves the existing Charleston Deep Artificial Reef MPA 1.4 mi (2.3 km) northwest to match the boundary of the U.S. Army Corps of Engineers' permitted artificial reef area at that location. This final rule does not change the size of the existing MPA. The Council originally designated the current area as an artificial reef site in Amendment 14 to the FMP (74 FR 1621, January 13, 2009). The State of South Carolina has worked with the U.S. Army Corps of Engineers to modify the boundary of this site to include material recently sunk by the state in the area and requested that the Council shift their boundary of the existing Charleston Deep Artificial Reef MPA to match the new boundary of the U.S. Army Corps of Engineers' permitted artificial reef area.

Management Measure Contained in Amendment 36 but Not Codified Through This Final Rule

In addition to the management measures that this final rule implements, Amendment 36 includes an action to modify the SMZ procedures in the FMP to allow for the designation of spawning SMZs. The Council will be able to designate important spawning areas as spawning SMZs to provide additional protection to some existing Essential Fish Habitat-Habitat Areas of Particular Concern for snapper-grouper species. The Council concluded that designating areas as spawning SMZs is important to protect snapper-grouper species and habitat where snapper-grouper species spawn. Additionally, the Council concluded that designating the spawning SMZ sites through this final rule, and subsequent changes to regulations, would enhance reproduction for snapper-grouper species and thus increase the number of eggs and larvae that are produced by the species.

Comments and Responses

NMFS received a total of 101 comments on the notice of availability and proposed rule for Amendment 36. The commenters included commercial, private recreational, and charter vessel fishing entities, as well as recreational divers, non-governmental organizations, and individuals from the general public. Comments both supported additional protections for spawning fish through

implementation of spawning SMZs and opposed the implementation of any spatial closures in the South Atlantic. The majority of comments received from the public during the comment period were supportive of the actions in Amendment 36 to establish spawning SMZs to protect spawning snapper-grouper species. NMFS' responses to comments that specifically relate to the actions contained in Amendment 36 and the proposed rule are summarized below.

Comment 1: NMFS should not establish additional fishing area closures to protect spawning fish. The data used to determine potential spawning SMZ sites are flawed and the sites were arbitrarily selected. Additionally, the science does not support the use of MPAs or similarly named spatial closures as a viable management option.

Response: NMFS disagrees that the spawning SMZ sites were arbitrarily selected and that the data used are flawed. The Council used a variety of data sources to select spawning SMZ sites. Data sources included the Southeast Reef Fish Survey, habitat mapping research, and cooperative research projects that identified locations where snapper-grouper species occur, including spawning fish. In addition, multiple groups provided input on site selection to protect spawning fish while reducing social and economic impacts to fishermen. These groups included fishermen on the Council's MPA Expert Work Group and Snapper-Grouper Advisory Panel (Snapper-Grouper AP) who could be affected by the spawning SMZs. Finally, the Council evaluated comments and recommendations from the public during meetings such as public hearings and scoping meetings. The NMFS Southeast Fisheries Science Center reviewed the data and analyses contained in Amendment 36 and certified it to be based on the best scientific information available.

NMFS disagrees that spatial closures are not a viable management option for protecting spawning snapper-grouper species. Areas closed to protect known spawning locations of fish species have been shown to provide positive biological and socio-economic benefits. The spawning SMZs implemented by this final rule are expected to result in additional protections for spawning snapper-grouper, while potentially providing positive economic effects by increasing future stock size and sustainability. Should monitoring efforts highlight the need for the adjustment of an area or the removal of a spawning SMZ if spawning snapper-grouper species are not documented in the area, this final rule will allow the Council to modify spawning SMZs. If the Council does not take any subsequent action to modify or renew the spawning SMZs, most of the spawning SMZs would expire automatically after the 10-year sunset provision in this final rule.

Comment 2: NMFS is establishing spawning SMZs without any regard for the economic and social impacts on fishermen and coastal communities.

Response: NMFS disagrees. The Magnuson-Stevens Act requires NMFS to consider and analyze the economic and social impacts of proposed management actions. Amendment 36 and this final rule recognize that negative short-term economic effects resulting from restrictions in fishing opportunities in the designated spawning SMZs may occur. The spawning SMZs are small (combined total area is 17.71 square miles) relative to all available fishing grounds in the South Atlantic, and the total estimated economic loss of ex-vessel revenue for the entire commercial sector is $1,605 annually. NMFS assumes that any reduction in ex-vessel revenue from this final rule would be minimized based on the small size of each spawning SMZ area and the high likelihood that commercial vessels would substitute landings of snapper-grouper species in other areas. Also, the allowance for transit and trolling for pelagic species could reduce economic impacts from this final rule to fishermen.

Comment 3: The spawning SMZs should be closed to all fishing methods. Research has shown that snapper-grouper species, including warsaw grouper and speckled hind, can be harvested through the deployment of trolling gear. Allowing trolling of any kind could undermine the potential effectiveness of a spawning SMZ and would make enforcement of the provision that allows transiting with snapper-grouper species on board difficult.

Response: Amendment 36 and this final rule allow fishermen to troll for pelagic species in the spawning SMZs but do not allow fishing vessels to have snapper-grouper species on board. The final rule allows fishing vessels to possess snapper-grouper species on board while in a spawning SMZ only if the vessel is transiting through the spawning SMZ directly and without stopping, and if fishing gear is appropriately stowed and unavailable for immediate use (*e.g.,* terminal gear, like hooks and weights, must be disconnected and stowed separately from a rod and reel). Therefore, law enforcement would be able to determine the difference between fishing vessels that are trolling for pelagic species and fishing vessels that are transiting the spawning SMZs with snapper-grouper species on board through visual inspection of the gear and the species on board. The trolling and transit allowances were discussed by the Council and included in Amendment 36 as a way to reduce the economic and social impacts of spatial closures on the fishing community and address concerns about safety at-sea, respectively.

Comment 4: Fishing for snapper-grouper species and anchoring in the spawning SMZs should be exempted for spear fishermen. Spear fishing is a selective gear type and large catches of snapper-grouper are not expected to occur through its use.

Response: In all of the spawning SMZs implemented by this final rule, the fishing for, harvest, or possession (except while transiting through a spawning SMZ) of snapper-grouper species is prohibited year-round. While NMFS agrees that spear fishing is a selective fishing gear with lower bycatch potential compared to other fishing methods, spear fishing could remove larger fish that are important to spawning. Prohibiting spear fishing in spawning SMZs is expected to provide protection to spawning snapper-grouper species to meet the objectives of Amendment 36.

Comment 5: Establishing Warsaw Hole as a spawning SMZ should be removed from consideration in Amendment 36. Fish caught in the Warsaw Hole and surrounding area (particularly greater amberjack) make up the majority of some fishermen's annual income in Key West, Florida, and fishing in the area results in little to no discards. Additionally, the majority of landings around Warsaw Hole occur north of 24°21′ N. lat., within the 1.8-square mile area included in another sub-alternative. However, if the Warsaw Hole Spawning SMZ must be established, the alternative consisting of a 0.9-square mile area is recommended over the preferred alternative of a 3.6-square mile area. The 0.9-square mile area would provide the least amount of negative economic impact to fishermen in Key West, Florida.

Response: The Council's objective for the protection of Warsaw Hole is to implement a spawning SMZ that would maximize the probability that snapper-grouper species, including warsaw grouper and greater amberjack, reform spawning aggregations at this site while balancing both short and long-term social and economic impacts to fishermen. To accomplish this objective,

the Council determined the spawning SMZ should cover the shelf edge around the hole where greater amberjack spawn. After evaluating a spawning SMZ of different sizes around Warsaw Hole, the Council concluded that the 3.6-square mile area for the Warsaw Hole Spawning SMZ best meets this objective.

NMFS acknowledges that there may be short-term negative social and economic impacts from the spawning SMZ being implemented for Warsaw Hole. The Council considered these economic impacts but determined that the enhanced reproduction for snapper-grouper species and, subsequently, the increased the number of eggs and larvae that are produced as a result of this added protection, would be expected to result in long-term indirect economic benefits to commercial and recreational fishermen. In the end, the Council concluded that the 3.6-square mile area for the Warsaw Hole Spawning SMZ best meets the objectives of Amendment 36 by creating positive impacts, while balancing both short and long-term social and economic impacts.

Comment 6: The Council should adopt the 3.6-square mile area as a spawning SMZ for Warsaw Hole and the 13.3-square mile area as a spawning SMZ for Daytona Steeples. These two alternatives together would provide the greatest amount of protection to spawning snapper-grouper species off Florida.

Response: The Council selected the 3.6-square mile area around Warsaw Hole as the only spawning SMZ off Florida. Extensive input from the Council's Snapper-Grouper AP and the public indicated that there would be support for a spawning SMZ at Daytona Steeples if there were data on spawning snapper-grouper species or habitat in the area. The Council considered a spawning SMZ in the Daytona Steeples area but agreed with the Snapper-Grouper AP and public about the lack of available data on spawning snapper-grouper species or habitat and decided not to propose any spawning SMZ in the Daytona Steeples area.

Comment 7: The details in the system management plan (SMP) for the spawning SMZs, such as cost, monitoring, and evaluation techniques, should have been fully developed before the proposed sites in Amendment 36 were presented to the Council.

Response: The SMP for the spawning SMZs was developed in conjunction with Amendment 36 to outline the data and research needed to monitor and evaluate the spawning SMZs and guide researchers applying for project funding. The SMP outlines the estimated project costs for each study type to aid fishery managers in determining research priorities. The purpose of the SMP is not to outline the specific methods and costs. The Council acknowledged that the SMP will likely be modified over time as research projects are implemented. One of the primary tasks for the SMP was to recommend development of an advisory panel to the Council. The advisory panel would be used to further develop specific projects to monitor spawning SMZs.

Classification

The Regional Administrator for the NMFS Southeast Region has determined that this final rule is consistent with Amendment 36, the FMP, the Magnuson-Stevens Act, and other applicable laws.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. Public comments relating to socio-economic implications and potential impacts on small businesses are addressed in the responses to Comments 2, 3, and 4 in the Comments and Responses section of this final rule. No comments were received regarding the certification and NMFS has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

Change to Codified Text From the Proposed Rule

In this final rule, NMFS makes one change to the coordinates table for the Devil's Hole/Georgetown Hole Spawning SMZ. In the proposed rule, the coordinate points for this spawning SMZ were listed in a counter-clockwise order when plotted on a map or chart. The points for all other coordinate tables of the spawning SMZs in the proposed rule were listed in a clockwise order. This final rule revises the order of the coordinates for the Devil's Hole/Georgetown Hole Spawning SMZ to list them in a clockwise order, to be consistent with the other spawning SMZs in this final rule.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Marine protected area, South Atlantic, Special management zone.

Dated: June 27, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.183, revise the table in paragraph (a)(1)(i)(D) and add paragraph (a)(2) to read as follows:

§ 622.183 Area and seasonal closures.

(a) * * *

(1) * * *

(i) * * *

(D) * * *

Point	North lat.	West long.
A	32°05.04′	79°13.575′
B	32°09.65′	79°09.2′
C	32°07.155′	79°05.595′
D	32°02.36′	79°09.975′
A	32°05.04′	79°13.575′

* * * * *

(2) *Spawning SMZs.* (i) Any fishing vessel in a spawning SMZ is prohibited to fish for or harvest species in the snapper-grouper fishery management unit year-round. For a fishing vessel to possess snapper-grouper species on board while in a spawning SMZ, the vessel must be in transit and fishing gear must be appropriately stowed, as specified in paragraph (a)(2)(vii) of this section. Except for spawning SMZs of Area 51 and Area 53, the spawning SMZs in this paragraph are effective until August 2, 2027. A person on board a fishing vessel may not anchor, use an anchor and chain, or use a grapple and chain while in the spawning SMZs specified in paragraph (a)(2) of this section. The anchoring prohibition does not apply to fishing vessels in the spawning SMZs of Area 51 and Area 53.

(ii) *South Cape Lookout Spawning SMZ* is bounded by rhumb lines connecting, in order, the following points:

Point	North lat.	West long.
A	33°53.040′	76°28.617′
B	33°52.019′	76°27.798′
C	33°49.946′	76°30.627′
D	33°51.041′	76°31.424′
A	33°53.040′	76°28.617′

(iii) *Devil's Hole/Georgetown Hole Spawning SMZ* is bounded by rhumb lines connecting, in order, the following points:

Point	North lat.	West long.
A	32°34.311′	78°34.996′
B	32°34.311′	78°33.220′
C	32°32.748′	78°33.220′
D	32°32.748′	78°34.996′
A	32°34.311′	78°34.996′

(iv) *Area 51 Spawning SMZ* is bounded by rhumb lines connecting, in order, the following points:

Point	North lat.	West long.
A	32°35.25′	79°28.6′
B	32°35.25′	79°27′
C	32°33.75′	79°27′
D	32°33.75′	79°28.6′
A	32°35.25′	79°28.6′

(v) *Area 53 Spawning SMZ* is bounded by rhumb lines connecting, in order, the following points:

Point	North lat.	West long.
A	32°22.65′	79°22.25′
B	32°22.65′	79°20.5′
C	32°21.15′	79°20.5′
D	32°21.15′	79°22.25′
A	32°22.65′	79°22.25′

(vi) *Warsaw Hole/50 Fathom Hole Spawning SMZ* is bounded by rhumb lines connecting, in order, the following points:

Point	North lat.	West long.
A	24°22.277′	82°20.417′
B	24°22.277′	82°18.215′
C	24°20.932′	82°18.215′
D	24°20.932′	82°20.417′
A	24°22.277′	82°20.417′

(vii) For the purpose of paragraph (a)(2)(i) of this section, transit means direct, non-stop progression through the spawning SMZ. Fishing gear appropriately stowed means—

(A) A longline may be left on the drum if all gangions and hooks are disconnected and stowed below deck. Hooks cannot be baited. All buoys must be disconnected from the gear; however, buoys may remain on deck.

(B) Trawl doors and nets must be out of the water, but the doors are not required to be on deck or secured on or below deck.

(C) A gillnet, stab net, or trammel net must be left on the drum. Any additional such nets not attached to the drum must be stowed below deck.

(D) Terminal gear (*i.e.,* hook, leader, sinker, flasher, or bait) used with an automatic reel, bandit gear, buoy gear, handline, or rod and reel must be disconnected and stowed separately from such fishing gear. Sinkers must be disconnected from the down rigger and stowed separately.

(E) A crustacean trap, golden crab trap, or sea bass pot cannot be baited. All buoys must be disconnected from the gear; however, buoys may remain on deck.

* * * * *

■ 3. In § 622.194, revise paragraph (a) to read as follows:

§ 622.194 Adjustment of management measures.

* * * * *

(a) Biomass levels, age-structured analyses, target dates for rebuilding overfished species, MSY (or proxy), OY, ABC, TAC, quotas (including a quota of zero), annual catch limits (ACLs), annual catch targets (ACTs), AMs, maximum fishing mortality threshold (MFMT), minimum stock size threshold (MSST), trip limits, bag limits, size limits, gear restrictions (ranging from regulation to complete prohibition), seasonal or area closures, fishing year, rebuilding plans, definitions of essential fish habitat, essential fish habitat, essential fish habitat HAPCs or Coral HAPCs, restrictions on gear and fishing activities applicable in essential fish habitat and essential fish habitat HAPCs, and establish or modify spawning SMZs.

* * * * *

[FR Doc. 2017–13751 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 170320292–7580–02]

RIN 0648–XF311

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

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

ACTION: Final rule.

SUMMARY: NMFS issues this rule to implement annual management measures and harvest specifications to establish the allowable catch levels (*i.e.,* annual catch limit (ACL)/harvest guideline (HG)) for the northern subpopulation of Pacific sardine (hereafter, Pacific sardine), in the U.S. exclusive economic zone (EEZ) off the Pacific coast for the fishing season of July 1, 2017, through June 30, 2018. These specifications were determined according to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). This action includes a prohibition on directed non-tribal Pacific sardine commercial fishing off the coasts of Washington, Oregon, and California, which is required because the estimated 2017 biomass of Pacific sardine has dropped below the biomass threshold specified in the HG control rule. Under this action, Pacific sardine may still be harvested as part of either the live bait or tribal fishery, or as incidental catch in other fisheries; the incidental harvest of Pacific sardine would initially be limited to 40-percent by weight of all fish per trip when caught with other CPS or up to 2 metric tons (mt) when caught with non-CPS. The ACL for the 2017–2018 Pacific sardine fishing year is 8,000 mt. This action is intended to conserve and manage the Pacific sardine stock off the U.S. West Coast.

DATES: Effective July 1, 2017 through June 30, 2018.

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034, *joshua.lindsay@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Pacific sardine fishery in the U.S. EEZ off the Pacific coast (California, Oregon, and Washington) in accordance with the CPS FMP. Annual specifications published in the **Federal Register** establish the allowable harvest levels (*i.e.,* overfishing limit (OFL)/ACL/HG) for each Pacific sardine fishing year. The purpose of this final rule is to implement these annual catch reference points for the 2017–2018 fishing year. This final rule adopts, without changes, the catch levels and restrictions that NMFS proposed in the rule published on May 30, 2017 (82 FR 24656), including the OFL and an acceptable biological catch (ABC) that takes into consideration uncertainty surrounding the current estimate of biomass for Pacific sardine in the U.S. EEZ off the Pacific coast.

The FMP and its implementing regulations require NMFS to set these annual catch levels for the Pacific sardine fishery based on the annual specification framework and control

rules in the FMP. These control rules include the HG control rule, which, in conjunction with the OFL and ABC rules in the FMP, are used to manage harvest levels for Pacific sardine, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* According to the FMP, the quota for the principal commercial fishery is determined using the FMP-specified HG formula. The HG formula in the CPS FMP is HG = [(Biomass − CUTOFF) * FRACTION * DISTRIBUTION] with the parameters described as follows:

1. *Biomass.* The estimated stock biomass of Pacific sardine age one and above. For the 2017–2018 management season, this is 86,586 mt.

2. *CUTOFF.* This is the biomass level below which no HG is set. The FMP established this level at 150,000 mt.

3. *DISTRIBUTION.* The average portion of the Pacific sardine biomass estimated in the EEZ off the Pacific coast is 87 percent.

4. *FRACTION.* The temperature-varying harvest fraction is the percentage of the biomass above 150,000 mt that may be harvested.

As described above, the Pacific sardine HG control rule, the primary mechanism for setting the annual directed commercial fishery quota, includes a CUTOFF parameter, which has been set as a biomass level of 150,000 mt. This amount is subtracted from the annual biomass estimate before calculating the applicable HG for the fishing year. Since this year's biomass estimate is below that value, the formula results in an HG of zero, and no Pacific sardine are available for the primary commercial directed fishery during the 2017–2018 fishing season.

At the April 2017 Pacific Fishery Management Council (Council) meeting, the Council's Science and Statistical Committee (SSC) approved, and the Council adopted, the ''Assessment of the Pacific Sardine Resource in 2017 for U.S. Management in 2017–2018,'' which was prepared by NMFS Southwest Fisheries Science Center. The resulting Pacific sardine biomass estimate of 86,586 mt is the best available science for setting harvest specifications. Based on recommendations from its SSC and other advisory bodies, the Council recommended, and NMFS is implementing, an OFL of 16,957 mt, an ABC of 15,497 mt, and a prohibition on Pacific sardine catch, unless it is harvested as part of either the live bait or tribal fishery or incidental to other fisheries for the 2017–2018 Pacific sardine fishing year. As additional management measures, the Council also recommended, and NMFS is implementing through this action, an ACL of 8,000 mt and that the incidental catch of Pacific sardine in other CPS fisheries be managed with the following automatic inseason actions to reduce the potential for both targeting and discard of Pacific sardine:

- An incidental per landing by weight allowance of 40 percent Pacific sardine in non-treaty CPS fisheries until a total of 2,000 mt of Pacific sardine are landed.
- When 2,000 mt are landed, the incidental per landing allowance will be reduced to 20 percent until a total of 5,000 mt of Pacific sardine have been landed.
- When 5,000 mt have been landed, the incidental per landing allowance will be reduced to 10 percent for the remainder of the 2017–2018 fishing year.

Pacific sardine is known to comingle with other CPS stocks; thus, these incidental allowances are established to allow for the continued prosecution of these other important CPS fisheries and reduce the potential discard of sardine. Additionally, an incidental per landing allowance is allowed in non-CPS fisheries: Up to 2 mt may be landed per trip.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** announcing the date of attainment of any of the incidental catch levels described above and subsequent changes to allowable incidental catch percentages. Additionally, to ensure that the regulated community is informed of any closure, NMFS will also make announcements through other means available, including fax, email, and mail to fishermen, processors, and state fishery management agencies.

As explained in the proposed rule, the Quinault Indian Nation requested a set-aside for tribal harvest of 800 mt (the same amount that was requested and approved for 2016–2017). NMFS considered this request and, per this action, 800 mt of the 2017–2018 ACL are being set aside for tribal harvest.

Detailed information on the fishery and the stock assessment are found in the report ''Assessment of the Pacific Sardine Resource in 2017 for U.S. Management in 2017–2018'' (see **FOR FURTHER INFORMATION CONTACT**).

Comment and Response

On May 30, 2017, NMFS published a proposed rule for this action and solicited public comments (82 FR 24656), with a public comment period that ended on June 14, 2017. NMFS received one comment letter—explained below—during the comment period. After consideration of the public comment, no changes were made from the proposed rule. For further background information on this action please refer to the preamble of the proposed rule. NMFS summarizes and responds below to the comment letter below.

Comment: The commenter expressed support for the prohibition on directed commercial sardine fishing, but opposition to the proposed ACL level, and requested that NMFS instead set an ACL of no more than 2,000 mt to be divided among the live bait and tribal sectors, and to accommodate limited bycatch. The commenter expressed an opinion that the proposed ACL of 8,000 mt is contrary to the purpose of the CUTOFF and that only minimal incidental catch (*i.e.,* 2,000 mt) should be allowed to prevent further depletion and support sardine recovery.

In addition to commenting on the proposed rule, the bulk of the comment described various scientific papers and requested reconsideration of various aspects of sardine management including the Minimum Stock Size Threshold value as well as aspects of the harvest guideline control rule, including but not limited to the existing CUTOFF parameter and the DISTRIBUTION parameter. (These parameters, as well as other changes to the sardine harvest control rule and management are set in the CPS Plan and are beyond the scope of this rulemaking; therefore, they will not be addressed below.)

Response: NMFS disagrees that the ACL implemented in this rule is not in line with the FMP or that it fails to prevent overfishing or ''is excessive and risks further depletion and delayed recovery''. The ACL should be viewed in the context of the OFL for the northern subpopulation of Pacific Sardine of 16,957 mt and an ABC of 15,497 mt that takes into account scientific uncertainty surrounding the OFL. These harvest reference limits were recommended by the Council based on the control rules in the FMP and were endorsed by the Council's SSC. The commenter does not question that the OFL and ABC levels reflect the best available science. By definition, harvest up to the level of OFL or ABC would not constitute overfishing, and would not drive the stock towards an overfished state. This rule takes a conservative approach by limiting harvest levels by all sources to an ACL of 8,000 mt, which is well below both the OFL and ABC. All incidental catch, live bait harvest and tribal harvest of sardine will be managed to stay at or below the ACL, employing multiple

safeguards to ensure the ACL will not be exceeded. In short, the management measures implemented by this rule are more than adequate to prevent exceeding the OFL. Additionally, even in the absence of any fishing mortality, unfavorable environmental conditions could keep the sardine population at a low level. Small pelagic species, such as sardine, undergo wide natural fluctuations in abundance, even in the absence of fishing, from environmental conditions external to fishing; therefore, it is highly unlikely that reducing the ACL from 8,000 mt to 2,000 mt would measurably affect long-term fluctuations in Pacific sardine abundance. Based on the recent stock assessments and NMFS research, low recent recruitments (*i.e.,* the number of young fish maturing into the spawning population) is the primary cause of the current downward trend in overall population size. Recruitment is believed to be strongly related to environmental conditions, particularly, large-scale oceanographic phenomena.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act, the NMFS West Coast Regional Administrator, with the concurrence of the Assistant Administrator, has determined that this final rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable laws.

NMFS finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for the establishment of these final harvest specifications for the 2017–2018 Pacific sardine fishing season. In accordance with the FMP, this rule was recommended by the Council at its meeting in April 2017, the contents of which were based on the best available new scientific information on the population status of Pacific sardine that became available at that time. Making these final specifications effective on July 1, 2017, is necessary for the conservation and management of the Pacific sardine resource. The FMP requires a prohibition on directed fishing for Pacific sardine for the 2017–2018 fishing year because the sardine biomass is below the CUTOFF. The purpose of the CUTOFF in the FMP—and prohibiting directed fishing when the biomass drops below this level—is to protect the stock when biomass is low and provide a buffer of spawning stock that is protected from fishing and available for use in rebuilding the stock. A delay in the effectiveness of this rule for a full 30 days would not allow the implementation of this prohibition prior to the expiration of the closure of the directed fishery on July 1, 2017, which was imposed under the 2016–2017 annual specifications.

Delaying the effective date of this rule beyond July 1 would be contrary to the public interest because reducing Pacific sardine biomass beyond the limits set out in this action could decrease the sustainability of the Pacific sardine, as well as cause future harvest limits to be even lower under the harvest control rule, thereby reducing future profits of the fishery.

These final specifications are exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This action does not contain a collection-of-information requirement for purposes of the Paper Reduction Act.

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

Dated: June 26, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–13685 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 170330338–7585–02]

RIN 0648–XF335

Pacific Island Fisheries; 2017–18 Annual Catch Limit and Accountability Measures; Main Hawaiian Islands Deep 7 Bottomfish

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

ACTION: Final specifications.

SUMMARY: NMFS specifies an annual catch limit (ACL) of 306,000 lb for Deep 7 bottomfish in the main Hawaiian Islands (MHI) for the 2017–18 fishing year, which will begin on September 1, 2017, and end on August 31, 2018. If NMFS projects that the fishery will reach the ACL, NMFS would close the commercial and non-commercial fisheries for MHI Deep 7 bottomfish for the remainder of the fishing year as an accountability measure (AM). The ACL and AM support the long-term sustainability of Hawaii bottomfish.

DATES: The final specifications are effective from July 31, 2017, through August 31, 2018.

ADDRESSES: Copies of the Fishery Ecosystem Plan for the Hawaiian Archipelago are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel. 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org.* Copies of the environmental assessment and finding of no significant impact for this action, identified by NOAA–NMFS–2017–0033, are available from *www.regulations.gov,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd. Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Sarah Ellgen, NMFS PIR Sustainable Fisheries, 808–725–5173.

SUPPLEMENTARY INFORMATION: Through this action, NMFS is specifying an ACL of 306,000 lb of Deep 7 bottomfish in the MHI for the 2017–18 fishing year. The fishing year begins September 1, 2017, and ends on August 31, 2018. The Council recommended this ACL, based on the best available scientific, commercial, and other information, taking into account the associated risk of overfishing. The ACL of 306,000 lb for 2017–18 is 12,000 lb less than the ACL that NMFS specified for 2016–17 (82 FR 5429, January 18, 2017).

The MHI Management Subarea is the portion of U.S. Exclusive Economic Zone around the Hawaiian Archipelago east of 161°20′ W. The Deep 7 bottomfish are onaga (*Etelis coruscans*), ehu (*E. carbunculus*), gindai (*Pristipomoides zonatus*), kalekale (*P. sieboldii*), opakapaka (*P. filamentosus*), lehi (*Aphareus rutilans*), and hapuupuu (*Hyporthodus quernus*).

NMFS will monitor the fishery and, if we project that the fishery will reach the ACL before August 31, 2018, we would, as an AM authorized in 50 CFR 665.4(f), close the non-commercial and commercial fisheries for Deep 7 bottomfish in Federal waters through August 31, 2018. During a fishery closure for Deep 7 bottomfish, no person may fish for, possess, or sell any of these fish in the MHI Management Subarea.

There is no prohibition on fishing for, possessing, or selling other (*non*-Deep 7) bottomfish during such a closure. All other management measures continue to apply in the MHI bottomfish fishery. If NMFS and the Council determine that the final 2017–18 Deep 7 bottomfish catch exceeds the ACL, NMFS would reduce the Deep 7 bottomfish ACL for 2018–19 by the amount of the overage.

You may review additional background information on this action in the preamble to the proposed specifications (82 FR 24092; May 25, 2017); we do not repeat that information here.

Comments and Responses

The comment period for the proposed specifications ended on June 9, 2017. NMFS did not receive any comments.

Changes From the Proposed Specifications

There are no changes in the final specifications from the proposed specifications.

Classification

The Regional Administrator, NMFS PIR, determined that this action is necessary for the conservation and management of MHI Deep 7 bottomfish, and that it is consistent with the Magnuson-Stevens Act and other applicable laws.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed specification stage that this action would not have a significant economic impact on a substantial number of small entities. NMFS published the factual basis for the certification in the proposed specifications, and does not repeat it here. NMFS did not receive comments regarding this certification. As a result, a final regulatory flexibility analysis is not required, and one was not prepared.

This action is exempt from review under Executive Order 12866.

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

Dated: June 26, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–13681 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 125
Friday, June 30, 2017

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

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2017–BT–TP–0004]

Energy Conservation Program: Test Procedures for Consumer Refrigerators, Refrigerator-Freezers, and Freezers

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

ACTION: Request for information (''RFI'').

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating a data collection process through this request for information to consider whether to amend DOE's test procedures for consumer refrigerators, refrigerator-freezers, and freezers. To inform interested parties and to facilitate this process, DOE has gathered data, identifying several issues associated with the currently applicable test procedures on which DOE is interested in receiving comment. The issues outlined in this document mainly concern testing products with newly-available features, the inclusion of automatic icemaker energy use, built-in product test configuration, any issues with the current test procedure that need to be addressed, and any additional topics that may inform DOE's decisions in a future test procedure rulemaking, including methods to reduce regulatory burden while ensuring the procedure's accuracy. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this request for information).

DATES: Written comments and information are requested and will be accepted on or before July 31, 2017.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–TP–0004, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* To *ConsumerRefrigFreezer2017TP0004@ee.doe.gov.* Include the docket number EERE–2017–BT–TP–0004 in the subject line of the message.
- *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–6636. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.
- *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., 6th Floor, Washington, DC, 20024. Telephone: (202) 586–6636. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section III of this document.

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

The docket Web page can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2017-BT-TP-0004.* The docket Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section III for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

Consumer refrigerators, refrigerator-freezers, and freezers are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(1)) DOE's test procedures for consumer refrigerators, refrigerator-freezers, and freezers are prescribed at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendices A and B (''Appendices A and B''). The following sections discuss DOE's authority to establish and amend test procedures for consumer refrigerators, refrigerator-freezers, and freezers, as well as relevant background information regarding DOE's consideration of test procedures for these products.

A. Authority and Background

The Energy Policy and Conservation Act of 1975 (''EPCA'' or ''the Act''),[1] Public Law 94–163 (42 U.S.C. 6311–6317, as codified), among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. Title III, part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include consumer refrigerators, refrigerator-freezers, and freezers, the subject of this request for information (RFI). (42 U.S.C. 6292(a)(1))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6291), energy conservation standards (42 U.S.C. 6295), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (See 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6316(b)(2)(D))

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

In addition, if DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including consumer refrigerators, refrigerator-freezers, and freezers, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6293(b)(1)(A)) If amended test procedures are appropriate, DOE must publish a final rule to incorporate the amendments. If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. DOE is publishing this RFI to collect data and information to inform a potential test procedure rulemaking to satisfy the 7-year review requirement specified in EPCA, which requires that DOE publish, by April 21, 2021, either a final rule amending the test procedures or a determination that amended test procedures are not required. (42 U.S.C. 6293(b)(1)(A))

B. Rulemaking History

DOE's current test procedures for refrigerators, refrigerator-freezers, and freezers are the result of numerous evolutionary steps taken since DOE initially established its test procedures for these products in a final rule published in the **Federal Register** on September 14, 1977 (42 FR 46140). Industry representatives viewed these original test procedures as too complex and eventually developed alternative test procedures in conjunction with the Association of Home Appliance Manufacturers (AHAM) that were incorporated into the 1979 version of HRF–1, ''Household Refrigerators, Combination Refrigerator-Freezers, and Household Freezers'' (HRF–1–1979). Using this industry-created test procedure, DOE revised its test procedures on August 10, 1982 (47 FR 34517).

On August 31, 1989, DOE amended the test procedure further when it published a final rule establishing test procedures for variable-defrost control refrigeration products, dual-compressor refrigerator-freezers, and freezers equipped with ''quick-freeze'' (54 FR 36238).

DOE amended the test procedures again on March 7, 2003, by modifying the test period used for products equipped with long-time automatic defrost or variable defrost (68 FR 10957).

On December 16, 2010, DOE made its most recent significant modifications to the test procedures when it published a final and interim final rule establishing the test procedures in Appendices A and B (75 FR 78810). That rule established a number of comprehensive changes to help improve the measurement of energy consumption of refrigerators, refrigerator-freezers, and freezers. These changes included, among other things: (1) Adjusting the standardized compartment temperatures and volume-adjustment factors, (2) adding new methods for measuring compartment volumes, (3) modifying the long-time automatic defrost test procedure to measure all energy use associated with the defrost function, and (4) adding test procedures for products with a single compressor and multiple evaporators with separate active defrost cycles. Lastly, the interim final rule addressed icemaking energy use by including a fixed energy use adder for those products equipped with an automatic icemaker. Using available data submitted by the industry, this value was set at 84 kilowatt-hours (kWh) per year. *Id.* On January 25, 2012, DOE finalized the test procedures established in the interim final rule and incorporated additional amendments to improve test accuracy (77 FR 3559).

On July 10, 2013, DOE proposed further amending the consumer refrigerator and refrigerator-freezer test procedure to address products with multiple compressors and to allow an alternative method for measuring and calculating energy consumption for refrigerator-freezers and refrigerators with freezer compartments, (78 FR 41610, ''2013 NOPR''). DOE also proposed to amend certain aspects of the consumer refrigerator, refrigerator-freezer, and freezer test procedures to ensure better accuracy and repeatability. Additionally, DOE solicited comment on a proposed automatic icemaker test procedure and on whether built-in

[1] All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015 (EEIA 2015), Public Law 114–11 (April 30, 2015).

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

products should be tested in a built-in configuration. *Id.* In response to the 2013 NOPR, interested parties requested that DOE grant more time to respond to the proposal for measuring energy use associated with icemaking and to DOE's request for comment regarding testing of built-in products in a built-in configuration. DOE granted the comment period extension request for these two topics (78 FR 53374, Aug. 29, 2013).

On April 21, 2014, DOE published a final rule for the refrigerator, refrigerator-freezer, and freezer test procedures (the ''2014 final rule''), (79 FR 22320). The amendments enacted by the 2014 final rule addressed products with multiple compressors and established an alternative method for measuring and calculating energy consumption for refrigerator-freezers and refrigerators with freezer compartments. The 2014 final rule also amended certain aspects of the test procedures to improve test accuracy and repeatability. To allow time to review comments and data received during the comment period extension, DOE did not address automatic ice making energy use or built-in testing configuration in the 2014 final rule. *Id.*

On July 18, 2016, DOE published a final rule that established coverage and test procedures for a variety of refrigeration products collectively described as ''miscellaneous refrigeration products'' (''MREFs''), (81 FR 46768). Included within this category are refrigeration products that include one or more compartments that maintain higher temperatures than typical refrigerator compartments, such as wine chillers and beverage coolers. Additionally, the final rule amended Appendices A and B to include provisions for testing MREFs and to improve the clarity of certain existing test requirements. *Id.*

II. Request for Information and Comments

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in the development of the technical and economic analyses regarding whether amended test procedures for consumer refrigerators, refrigerator-freezers, and freezers may be warranted. Specifically, DOE is requesting comment on any opportunities to streamline and simplify testing requirements for refrigerators, refrigerator-freezers, and freezers.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document. In particular, DOE notes that under E.O. 13771, executive branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017) (E.O. 13771 ''Reducing Regulation and Controlling Regulatory Costs''). Pursuant to that executive order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to consumer refrigerators, refrigerator-freezers, and freezers consistent with the requirements of EPCA.

A. Features

1. Door-in-Door Designs

DOE's test procedures for refrigerators, refrigerator-freezers, and freezers are intended to represent operation in typical room conditions with door openings by testing at an elevated ambient temperature with no door openings. 10 CFR 430.23(a)(7). The increased thermal load from the elevated ambient temperature is intended to represent the thermal load that would be associated with both door openings as cool cabinet air mixes with warmer ambient air and the loading of warmer items in the cabinet.

DOE is aware of certain products available on the market that incorporate a door-in-door design. This feature allows the consumer to access items loaded in the door shelves without opening an interior door that encloses the inner cabinet. This feature prevents the majority of the cool cabinet air from escaping to the room and being replaced by warmer ambient air, as would be the case during a typical total door opening.

Because the DOE test procedure requires testing with the cabinet doors remaining closed, it would not reflect the potential energy savings associated with door-in-door features during typical consumer operation with door openings.

DOE requests comment on test methods for products with door-in-door designs that will yield accurate and repeatable results. Specifically, DOE seeks information on whether an alternate test method is appropriate or whether potential energy savings may be addressed with a calculation approach. DOE also seeks information regarding what steps, if any, manufacturers are taking to account for the energy use characteristics of products that use door-in-door designs. Further, DOE requests data, if any, on consumer use of the door-in-door feature, including how often the outer door is used in comparison to a total door opening, and the corresponding energy impacts of each type of door opening.

2. Display Screens and Connected Functions

Many refrigerators, refrigerator-freezers, and freezers currently available on the market include user control panels or displays located on the front of the product. These features, which can control the products' function and provide additional user features, such as television or internet access, operate with many different control schemes, including activation by proximity sensors.

The DOE test procedure, by referencing AHAM's 2008 version of ''Energy and Internal Volume of Refrigerating Appliances'' (HRF–1–2008), requires testing with customer-accessible features, not required for normal operation, which are electrically powered, manually initiated, and manually terminated, set at their lowest energy usage positions when adjustment is provided.

However, by testing in this manner (*i.e.,* setting consumer features in their lowest energy positions), the resulting measurements may not accurately represent actual consumer use. DOE requests information on how consumers typically use exterior display screens and control panels, when available. While any information would be welcome, DOE is particularly interested in any survey data that may yield insight into the manner and frequency with which consumers use these features. Additionally, DOE requests detailed feedback on the appropriate energy-related settings to use for these types of features during testing to best represent consumer use.

Similarly, many products incorporating these more advanced user interfaces include internet connections to allow for additional functions. The product controls may consume different amounts of energy depending on whether the internet connection is enabled or disabled, and if enabled, whether it is connected to a network. DOE requests information (such as survey data) on whether consumers typically use an internet connection, when available, for refrigerators, refrigerator-freezers, and freezers. DOE also requests information on the potential energy impacts of the refrigeration products equipped with a connected configuration, and on the appropriate energy-related settings to use for testing.

B. Icemaking Energy Consumption

In 2010, DOE initiated a test procedure rulemaking to help address a

variety of test procedure-related issues, including energy use associated with automatic icemaking. On May 27, 2010, DOE published a NOPR (the ''2010 NOPR'') proposing to use a fixed value of 84 kWh per year to represent the energy use associated with automatic icemaking (75 FR 29824). The 2010 NOPR also indicated that DOE would consider adopting an approach based on testing to determine icemaking energy use if a suitable test procedure could be developed. *Id.* at 29846–29847. A broad group of interested parties submitted a joint comment supporting DOE's proposal to use a temporary fixed placeholder value to represent the energy use of automatic icemakers. The joint commenters also urged DOE to initiate a rulemaking no later than January 1, 2012, and publish a final rule no later than December 31, 2012, to amend the test procedures to incorporate a laboratory-based measurement of icemaking energy use. (Test Procedure for Refrigerators, Refrigerator-Freezers, and Freezers, Docket Number EERE–2009–BT–TP–0003; Joint Comment, No. 20 at pp. 5–6)

In January 2012, AHAM provided DOE with a draft test procedure that could be used to measure automatic icemaker energy usage. (AHAM Refrigerator, Refrigerator-Freezer and Freezer Ice Making Energy Test Procedure, Revision 1.0—12/14/11, No. 4) [3] AHAM then submitted a revised automatic icemaker test procedure on July 18, 2012. (AHAM Refrigerator, Refrigerator-Freezer and Freezer Ice Making Energy Test Procedure, Revision 2.0—7/10/12, No. 5) [4] In the subsequent 2013 NOPR, as mentioned in section I.B of this document, DOE proposed a method for measuring the energy usage associated with automatic icemaking based on the revised approach submitted by AHAM. See generally 78 FR 41618–41629. In response to the 2013 NOPR, AHAM submitted comments to DOE requesting that DOE grant its members more time to respond to the automatic icemaker testing proposal, which DOE granted (78 FR 53374, Aug. 29, 2013). In the 2014 final rule, DOE established the fixed value adder approach and stated that it would review comments received during the comment period extension to address the icemaking test procedure issue in a future notice. See 79 FR 22341–22342.

A number of interested parties supported the development and adoption of a test procedure that measures the energy use of automatic icemaking. These commenters cited a number of reasons to justify a laboratory-based icemaker energy test procedure, including: (1) A direct laboratory test is more accurate and representative of actual icemaking energy use, and (2) the fixed adder approach would not reward improvements in icemaking efficiency or provide incentives to reduce icemaker energy consumption. (BSH Home Appliances Corporation, No. 21 at p. 1; [5] Joint Commenters,[6] No. 42 at pp. 1–5; Samsung Electronics America, Inc., No. 39 at p. 2)

Other interested parties supported the adder approach, noting the significant test burden associated with the proposed icemaking test procedure and the limited opportunities to reduce icemaking energy consumption. (AHAM, No. 37 at p. 2–5; GE Appliances, No. 40 at p. 5; Sub-Zero Group, Inc., No. 36 at p. 2) Further, DOE received data indicating that consumers likely use less ice than assumed in calculating the 84 kWh/year adder. Interested parties commented that the updated consumer use data supported an adder as low as 28 kWh/year. (AHAM, No. 37 at pp. 2–6; GE Appliances, No. 40 at pp. 2–4; Northwest Energy Efficiency Alliance and Northwest Power & Conservation Council, No. 41 at p. 2)

DOE welcomes additional feedback from interested parties on the most appropriate approach to account for icemaker energy use. DOE also requests any more recent consumer use data, if available, regarding ice consumption and automatic icemaker usage in consumer refrigerator-freezers and freezers. DOE also seeks input regarding whether retention of the current fixed adder approach should continue or whether an actual test procedure should replace it at this time. If DOE were to adopt a test procedure that measures icemaker energy use, DOE seeks input on which one to use, for example, the test proposed in the 2013 NOPR, and what specific technical issues it needs to consider if it were to propose such a rule for adoption. To this end, DOE is also interested in what impacts, if any, the adoption of an icemaking energy measurement test procedure would have on the measured energy use of a given product when compared to the fixed energy value adder approach used in the current test procedure.

DOE is also aware of consumer products available on the market that use two automatic icemakers. Typically, these products are refrigerator-freezers with bottom-mounted freezers, with an icemaker in the freezer compartment and another contained in the through-the-door ice service in the fresh food compartment. The fresh food icemaker serves more frequent through-the-door ice service, while the freezer icemaker serves as an in-freezer storage container for infrequent bulk ice use.

DOE requests information on whether products with multiple automatic icemakers should be tested differently than the more typical single automatic icemaker models—and if so, how. DOE seeks consumer use data for these products to inform whether a different energy use adder or test procedure would be appropriate for these dual-icemaker products.

C. Built-In Test Configuration

In the 2013 NOPR, DOE presented data indicating that testing in a built-in enclosure may affect energy consumption for certain configurations of built-in products. Specifically, those products that reject condenser heat at the back of the unit showed a potential increase in energy use when tested in an enclosure. DOE observed no significant change in energy use associated with the test configuration for those products that reject heat from the front of the unit. DOE requested comment on the appropriate test configuration for built-in refrigerators, refrigerator-freezers, and freezers, (78 FR 46149–46150). Similar to the icemaking test issue, DOE provided additional time to comment on the built-in testing issue prior to the 2014 final rule, but did not address the issue in that rule.

In the rulemaking leading to the 2014 final rule, DOE received multiple comments. Some commenters supported testing built-in products in an enclosure, as this would represent how the products are used in the field. (Joint Commenters, No. 42 at pp. 5–6; Northwest Energy Efficiency Alliance and Northwest Power & Conservation Council, No. 41 at p. 4) Others opposed the enclosure approach, noting the significant increase in test burden with little or no corresponding change in

[3] Document No. 4 in Docket No. EERE–2012–BT–TP–0016, available for review at *www.regulations.gov*.

[4] Document No. 5 in Docket No. EERE–2012–BT–TP–0016, available for review at *www.regulations.gov*.

[5] A notation in the form ''BSH Home Appliances Corporation, No. 21 at p. 1'' identifies a written comment: (1) Made by BSH Home Appliances Corporation; (2) recorded in document number 21 that is filed in the docket of the test procedure rulemaking (Docket No. EERE–2009–BT–TP–0003) and available for review at *www.regulations.gov;* and (3) which appears on page 1 of document number 21.

[6] ''Joint Commenters'' refers to the Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Consumer Federation of America, National Consumer Law Center, and Natural Resources Defense Council.

measured energy consumption. These interested parties also noted that for the products showing a difference in measured energy use between the freestanding and enclosure setups, the enclosure configuration that DOE used (based on Underwriters Laboratories (UL) 250, ''Household Refrigerators and Freezers'') was not necessarily consistent with manufacturer installation instructions. (AHAM, No. 37 at pp. 16–17; BSH Home Appliances Corporation, No. 21 at p. 1; Liebherr-Canada, Ltd., No. 34 at pp. 1–4; Sub-Zero Group, Inc., No. 36 at p. 2).

DOE continues to seek comment on the built-in testing issue, including consumer installation, test burden, and energy impacts. Among the issues of interest to DOE include whether testing a product in its built-in condition would generally be more representative of energy consumption of a product during its average use cycle or period of use and, if so, the extent to which testing in this condition would be expected to affect the measured energy use of these products, if any. DOE requests information on whether testing all built-in products in an enclosure is appropriate, or whether testing in an enclosure would affect the test results only for certain built-in product configurations, such as those that exhaust condenser heat from the rear of the product. DOE is also interested in detailed information on whether there would be a significant additional test burden resulting from a requirement that specifies these products be tested in a built-in condition—and if so, the nature and extent of that burden. Additionally, DOE is interested in whether alternative methods of assessing the energy consumption of built-in products during their average use cycle or period of use, such as through a calculation or adder approach, are feasible—and if so, what likely degree of accuracy could be obtained if such methods were used in lieu of testing in a built-in condition.

D. Test Procedure Clarifications

1. Thermocouple Configuration for Freezer Drawers

As discussed in section II.A.2 of this document, Appendices A and B incorporate by reference portions of HRF–1–2008 for testing requirements. Section 5.5.5.5 of HRF–1–2008 includes figures specifying thermocouple placement for a number of example fresh food and freezer compartment configurations. HRF–1–2008 also notes that in situations where the interior of a cabinet does not conform to the configurations shown in the example figures, measurements must be taken at locations chosen to represent approximately the entire cabinet.

HRF–1–2008 provides a specific thermocouple location diagram for freezer compartments in refrigerator-freezers (type 6 in Figure 5–2). However, the diagram for this configuration is based on an upright, front-opening freezer compartment, and does not explicitly address drawer-type freezer compartments. Based on its experience testing these products at third-party test laboratories, DOE understands there may be confusion over which thermocouple layout is appropriate for drawer-type freezer compartments in refrigerator-freezers. DOE believes that sensor layout type 6 is appropriate for testing drawer freezer compartments in refrigerator-freezers. DOE requests feedback on whether this sensor layout or, alternatively, a different thermocouple configuration set forth in HRF–1–2008 or elsewhere, is appropriate for testing drawer freezer compartments.

2. Definitions

As discussed in the recent MREF test procedure final rule, DOE's test procedures in Appendices A and B frequently use the term ''compartment'' despite that term not being defined. While DOE considered the need for clarifying that term, it did not define it in that final rule. See 81 FR 46779.

DOE is aware of only one specific definition for ''compartment'' in finalized international or industry test procedures—specifically, Australian/New Zealand testing standard AS/NZS 4474.1–2007. This procedure define a compartment as ''an enclosed space within a refrigerating appliance, which is directly accessible through one or more external doors. A compartment may contain one or more sub-compartments and one or more convenience features.'' AS/NZS 4474.1–2007 further defines a ''sub-compartment'' as ''a permanent enclosed space within a compartment or sub-compartment which is designated as being a different type of food storage space (*i.e.,* has a different compartment temperature range) from the compartment or sub-compartment within which it is located,'' and ''convenience features,'' as enclosures or containers with temperature conditions which may or may not be different from the compartment within which they are located.

However, DOE notes that the AS/NZS 4474.1–2007 approach is not fully consistent with all of the uses of the term ''compartment'' currently found in the DOE test procedures. In some cases, the term denotes all of the space within a refrigeration product that operates within a designated temperature range. In other cases, the term refers to specific enclosed spaces that operate within a designated temperature range. For example, Appendix A, section 5.1.3 uses the term in both ways, referring to individual fresh food compartment temperatures and volumes to calculate the overall fresh food compartment temperature.

DOE requests information on whether the clarity of Appendices A and B would be improved by defining the term ''compartment'' and using the term consistently throughout the test procedures. If DOE were to define the term ''compartment,'' DOE seeks comment on what that definition should be—and whether a definition such as the one included in AS/NZS 4474.1–2007 would be sufficient to clearly define this term.

DOE also notes that while Appendix A defines ''cooler compartment,'' it does not directly define related terms such as ''fresh food compartment'' or ''freezer compartment''—although these definitions are in HFR–1–2008, which is incorporated by reference into Appendices A and B. 10 CFR 430.3. DOE requests comment on whether it should directly define these terms in Appendix A—and if so, how?

DOE also welcomes feedback on the definitions of ''refrigerators,'' ''refrigerator-freezers,'' and ''freezers'' in 10 CFR 430.2. These definitions were most recently amended in DOE's final rule establishing coverage and test procedures for MREFs, (81 FR 46768). Prior to that final rule, DOE published a supplemental noticed of proposed determination (''SNOPD'') in which it proposed to amend these definitions. In that SNOPD, DOE noted that the refrigerator and refrigerator-freezer product definitions described a freezer compartment as a compartment designed for the freezing and storage of food at temperatures below 8 °F which may be adjusted by the user to a temperature of 0 °F or below, and proposed to amend the definitions to refer to a compartment capable of maintaining compartment temperatures of 0 °F or below, (81 FR 11454, 11460, March 4, 2016). However, because interested parties commented that the proposed amendments may affect the scope of the existing refrigerator, refrigerator-freezer, and freezer definitions (AHAM, MREF Coverage No. 24 at pp. 2–3; [7] Sub Zero, MREF

[7] A notation in the form ''AHAM, MREF Coverage No. 24 at pp. 2–3'' identifies a written comment: (1) Made by the Association of Home Appliance

Coverage No. 22 at pp. 1–2), DOE did not adopt these proposed modifications to the amended definitions. See 81 FR 46777.

The proposed amendments would have resolved an inconsistency between the definitions and the standardized compartment temperature specified in the test procedure. Specifically, while the 8 °F threshold for freezer compartments in the definitions for refrigerators and refrigerator-freezers is consistent with the fresh food compartment and freezer compartment definitions included in HRF–1–2008, Appendix A requires that freezer compartments in refrigerator-freezers be tested to a standardized compartment temperature of 0 °F. Under the existing requirements, a product would meet the refrigerator-freezer definition but would not receive an energy use rating under Appendix A if the freezer compartment is capable of achieving a temperature below 8 °F but above 0 °F.

DOE requests feedback on whether it should address this potential definitional and testing issue, and if so, how. DOE also seeks information on how to best harmonize the refrigerator and refrigerator-freezer definitions with any potential updates to the fresh food and freezer compartment definitions.

E. AHAM HRF–1 Standard

As discussed in section II.A.2 of this document, the DOE test procedures incorporate by reference certain sections of the AHAM industry standard HRF–1–2008. DOE references HRF–1–2008 for definitions, installation and operating conditions, temperature measurements, and volume measurements. In August 2016, AHAM released an updated version of the HRF–1 standard, HRF–1–2016. Based on review of the newer standard, DOE notes that the majority of the updates from the 2008 standard are clarifications or other revisions that harmonize with DOE's test procedures. Accordingly, DOE does not expect that updating its references to HRF–1–2016 would substantively affect the test procedures in Appendices A and B.

DOE requests feedback on whether its test procedures should incorporate by reference certain sections of the most current version of HRF–1, HRF–1–2016, rather than HRF–1–2008. DOE also requests whether any of the revisions between HRF–1–2008 and HRF–1–2016 would substantively affect the requirements currently incorporated by reference in Appendices A and B—and if so, how?

F. Other Test Procedure Topics

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of the existing test procedures for refrigerators, refrigerator-freezers, and freezers not already addressed by the specific areas identified in this document. DOE particularly seeks information that would improve the repeatability, reproducibility, and consumer representativeness of the test procedures. DOE also requests information that would help DOE create a procedure that would limit manufacturer test burden through streamlining or simplifying testing requirements. Comments regarding repeatability and reproducibility are also welcome.

DOE also requests feedback on any potential amendments to the existing test procedure that could be considered to address impacts on manufacturers, including small businesses. Regarding the Federal test method, DOE seeks comment on the degree to which the DOE test procedure should consider and be harmonized with the most recent relevant industry standards for consumer refrigerators, freezers, and refrigerator-freezers and whether there are any changes to the Federal test method that would provide additional benefits to the public.

Additionally, DOE requests comment on whether the existing test procedures limit manufacturer's ability to provide additional features to consumers on refrigerators, refrigerator-freezers, and freezers. DOE particularly seeks information on how the test procedures could be amended to reduce the cost of these new or additional features and make it more likely that such features are included on consumer refrigerators, freezers, and refrigerator-freezers.

III. Submission of Comments

DOE invites all interested parties to submit in writing by July 31, 2017, comments and information on matters addressed in this notice and on other matters relevant to DOE's consideration of amended test procedures for refrigerators, refrigerator-freezers, and freezers. After the close of the comment period, DOE will begin collecting data, conducting analyses, and reviewing the public comments, as needed. These actions will be taken to aid in the development of a test procedure NOPR for refrigerators, refrigerator-freezers, and freezers if DOE determines that amended test procedures may be appropriate for these products.

Submitting comments via *http://www.regulations.gov.* The *http://www.regulations.gov* Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead,

Manufacturers; (2) recorded in document number 24 that is filed in the docket of the MREF coverage determination rulemaking (Docket No. EERE–2011–BT–DET–0072–0024) and available for review at *www.regulations.gov;* and (3) which appears on pages 2–3 of document number 24.

provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of the rulemaking process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the rulemaking process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this rulemaking should contact Appliance and Equipment Standards Program staff at (202) 586–6636 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Issued in Washington, DC, on June 23, 2017.

Kathleen B. Hogan,

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

[FR Doc. 2017–13803 Filed 6–29–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9568; Directorate Identifier 2016–NM–150–AD]

RIN 2120–AA64

Airworthiness Directives; 328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposal for an airworthiness directive (AD) for certain 328 Support Services GmbH Model 328–100 and Model 328–300 airplanes. This action revises the notice of proposed rulemaking (NPRM) by expanding the applicability and making certain inspections repetitive. We are proposing this AD to address the unsafe condition on these products. Since these actions impose an additional burden over those proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: The comment period for the NPRM published in the **Federal Register** on January 11, 2017 (82 FR 3217), is reopened.

We must receive comments on this SNPRM by August 14, 2017.

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

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

For service information identified in this SNPRM, contact 328 Support Services GmbH, Global Support Center, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; telephone +49 8153 88111 6666; fax +49 8153 88111 6565; email *gsc.op@328support.de;* Internet *http://www.328support.de.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9568; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9568; Directorate Identifier 2016–NM–150–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain 328 Support Services GmbH Model 328–100 and Model 328–300 airplanes. The NPRM published in the **Federal Register** on January 11, 2017 (82 FR 3217). The NPRM was prompted by reports of broken bonding wires of certain fuel line clamps. The NPRM proposed to require a one-time inspection of certain fuel line clamps for discrepancies, and replacement of any discrepant clamps.

Actions Since the NPRM Was Issued

Since we issued the NPRM, we have determined that repetitive inspections are necessary to address the unsafe condition and that additional airplanes are affected by the unsafe condition and must be added to the applicability.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0016, dated January 31, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition on all 328 Support Services GmbH Model 328–100 and Model 328–300 airplanes. The MCAI states:

> Occurrences of broken bonding wires of the fuel line clamps have been reported on Dornier 328–100 and Dornier 328–300 aeroplanes equipped with fuel line clamps Part Number (P/N) 14C02–10A, or P/N 14C02–12A, or P/N 14C02–16A. The affected fuel line clamps have been installed in accordance with the instructions of Dornier 328 Service Bulletin (SB) SB–328–28–490 or SB–328J–28–241, as applicable, to reduce occurrences of fuel line chafing.
>
> The results of the investigation did not identify design deficiency or production failure of the fuel line clamps. It is assumed that the chafing and breaking of the bonding wires are caused either by excessive vibration, misalignment, excessive installation tolerances or mistakes on installation or a combination thereof.
>
> This condition, if not detected and corrected, could lead to the loss of bonding function and, in combination with a lightning strike, create a source of ignition in a fuel tank, possibly resulting in a fire or explosion and consequent loss of the aeroplane.
>
> To address the unsafe condition, 328 Support Services issued Alert SB (ASB) ASB–328–28–041 (for Dornier 328–100) and ASB–328J–28–018 (for Dornier 328–300), providing inspection instructions.
>
> Consequently, EASA issued AD 2016–0169 [which corresponds to the NPRM] to require a one-time inspection of the fuel line clamps and, depending on findings, replacement. That [EASA] AD also required the reporting off all inspection results to the design approval holder.
>
> Since that [EASA] AD was issued, it was determined that repetitive inspections are necessary and 328 Support Services revised the applicable ASBs accordingly.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2016–0169, which is superseded, and requires repetitive inspections of all Hydraflow fuel line clamps [*i.e.,* a general visual inspection of all Hydraflow fuel line clamps for worn and missing bonding wires; a general visual inspection of the jet pump outlet, connection part, and fuel lines for chafing marks; and a measurement of the depth of the chafing marks on affected parts] and continued reporting to the TC Holder.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9568.

Related Service Information Under 1 CFR Part 51

328 Support Services has issued Alert Service Bulletin ASB–328J–28–018, Revision 2, dated December 12, 2016; and Alert Service Bulletin ASB–328–28–041, Revision 2, dated December 12, 2016. The service information describes procedures for a general visual inspection of all Hydraflow fuel line clamps for worn and missing bonding wires; a general visual inspection of the jet pump outlet, connection part, and fuel lines for chafing marks; a measurement of the depth of the chafing marks, and replacement of affected parts. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Comments

We gave the public the opportunity to participate in developing this proposed AD. We considered the comments received.

Request To Refer to Updated Service Information

Two commenters, Patrick Brady and Christoph Thallmayr, requested that we revise the proposed AD to refer to the latest 328 Support Services Service Bulletins. The commenters stated that updated versions of the service information specify repetitive inspections at intervals of 2,500 flight hours. The commenters further noted that EASA issued an updated AD, which references the latest service information. Patrick Brady noted that the repetitive inspections could be scheduled with recurring ''5A'' inspections to ensure no additional downtime is needed.

We agree with the request. We have revised this AD to refer to the updated service information and MCAI.

FAA's Determination and Requirements of This SNPRM

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Costs of Compliance

We estimate that this SNPRM affects 25 airplanes of U.S. registry

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	8 work-hours × $85 per hour = $680 per inspection cycle..	$0	$680 per inspection cycle	$17,000 per inspection cycle
Reporting	1 work-hour × $85 per hour = $85 per inspection cycle.	0	$85 per inspection cycle	$2,125 per inspection cycle

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	Up to 1 work-hour × $85 per hour = $85	Up to $588	Up to $673.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this proposed AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH): Docket No. FAA–2016–9568; Directorate Identifier 2016–NM–150–AD.

(a) Comments Due Date

We must receive comments by August 14, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to 328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) airplanes, certificated in any category, as identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model 328–100 airplanes, all serial numbers.

(2) Model 328–300 airplanes, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by reports of broken bonding wires of certain fuel line clamps. We are issuing this AD to prevent the loss of bonding function, which, in combination with a lightning strike, could create a source of ignition in a fuel tank, possibly resulting in a fire or explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Repetitive Inspections

Within 6 months after the effective date of this AD, do a general visual inspection of all Hydraflow fuel line clamps for worn and missing bonding wires; do a general visual

inspection of the jet pump outlet, connection part, and fuel lines for chafing marks; and for parts with chafing marks, before further flight, measure the depth of the chafing marks; in accordance with the Accomplishment Instructions of the service information specified in paragraph (g)(1) or (g)(2) of this AD, as applicable. Repeat the inspections thereafter at intervals not to exceed 2,500 flight hours.

(1) 328 Support Services GmbH Alert Service Bulletin ASB–328–28–041, Revision 2, dated December 12, 2016 (for Model 328–100 airplanes).

(2) 328 Support Services GmbH Alert Service Bulletin ASB–328J–28–018, Revision 2, dated December 12, 2016 (for Model 328–300 airplanes).

(h) Replacement of Parts

(1) If any worn or missing bonding wires are found during any inspection required by paragraph (g) of this AD, before further flight, replace all affected clamps, in accordance with the Accomplishment Instructions of the service information specified in paragraph (g)(1) or (g)(2) of this AD, as applicable.

(2) If, during any inspection required by paragraph (g) of this AD, any chafing depth is found that is more than the replacement limits specified in the Accomplishment Instructions of the service information specified in paragraph (g)(1) or (g)(2) of this AD, as applicable, before further flight, replace all affected parts, in accordance with the Accomplishment Instructions of the service information specified in paragraph (g)(1) or (g)(2) of this AD, as applicable.

(i) Reporting

At the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, report the inspection results, positive or negative, to 328 Support Services, GmbH, Global Support Center, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; fax +49 8153 88111 6565; email *gsc.op@328support.de.* The report must include findings on fuel line clamps, aircraft serial number, total flight hours, and total landings.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the initial inspection, parts replacement, and initial report required by paragraphs (g), (h), and (i) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (j)(1) through (j)(4) of this AD.

(1) 328 Support Services GmbH Alert Service Bulletin ASB–328–28–041, dated June 14, 2016.

(2) 328 Support Services GmbH Alert Service Bulletin ASB–328–041, Revision 1, dated October 13, 2016.

(3) 328 Support Services GmbH Alert Service Bulletin ASB–328J–28–018, dated June 3, 2016.

(4) 328 Support Services GmbH Alert Service Bulletin ASB–328J–28–018, Revision 1, dated October 13, 2016.

(k) No Terminating Action

Replacement of clamps as required by paragraph (h) of this AD does not constitute terminating action for the repetitive inspections required by paragraph (g) of this AD for that airplane.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Branch, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or 328 Support Services GmbH's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0016, dated January 31, 2017, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9568.

(2) For more information about this AD, contact Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149.

(3) For service information identified in this AD, contact 328 Support Services GmbH, Global Support Center, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; telephone +49 8153 88111 6666; fax +49 8153 88111 6565; email *gsc.op@328support.de;* Internet *http://www.328support.de.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 22, 2017.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–13756 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0628; Directorate Identifier 2016–NM–207–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A310 series airplanes. This proposed AD was prompted by a revision of certain airworthiness limitation items (ALI) documents, which require more restrictive maintenance requirements and airworthiness limitations. This proposed AD would require revising the maintenance or inspection program to incorporate the maintenance requirements and airworthiness limitations. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 14, 2017.

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

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

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0628; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–0628; Directorate Identifier 2016–NM–207–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2016–0217, dated November 2, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A310 series airplanes. The MCAI states:

> The airworthiness limitations for Airbus A310 aeroplanes, which are approved by EASA, are currently defined and published in the Airbus A310 Airworthiness Limitations Section (ALS) document(s). These instructions have been identified as mandatory actions for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> EASA previously issued [EASA] AD 2014–0124 (later revised) [which includes actions for Airbus A310 series airplanes; those actions are included in FAA AD 2013–13–13, Amendment 39–17501 (79 FR 48957, August 19, 2014) (''AD 2013–13–13'')], to require the actions as specified in Airbus A310 Airworthiness Limitation Item (ALI) Document at issue 08.
>
> Since EASA AD 2014–0124R1 was issued, Airbus replaced ALI Document issue 08 with A310 ALS Part 2 Revision 01 and then published the A310 ALS Part 2 Variation 1.1 and Variation 1.2, to introduce more restrictive maintenance requirements and/or airworthiness limitations.
>
> For the reason described above, this [EASA] AD retains part of the requirements of EASA AD 2014–0124R1, which will be superseded, and requires accomplishment of the actions specified in Airbus A310 ALS Part 2 Revision 01, ALS Part 2 Variation 1.1 and ALS Part 2 Variation 1.2 (hereafter collectively referred to as 'the ALS' in this [EASA] AD). The remaining requirements of EASA AD 2014–0124R1 are retained in [EASA] AD 2016–0218, applicable to A300–600 aeroplanes, published at the same time as this [EASA] AD.

This NPRM would not supersede AD 2013–13–13. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require revising the maintenance or inspection program to incorporate the maintenance requirements and airworthiness limitations. Accomplishment of the proposed actions would then terminate all requirements of AD 2013–13–13.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0628.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information:

- Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT—ALI),'' Revision 01, dated August 7, 2015.
- Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT—ALI),'' Variation 1.1, dated January 25, 2016.
- Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT—ALI),'' Variation 1.2, dated July 22, 2016.

The service information describes airworthiness limitations applicable to the DT—ALIs. These documents are distinct because they contain different tasks at different revision levels. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

This AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this proposed AD. The request should include a description of changes to the required

actions that will ensure the continued damage tolerance of the affected structure.

Costs of Compliance

We estimate that this proposed AD affects 8 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Maintenance Program Revision	1 work-hour × $85 per hour = $85	None	$85	$680

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2017–0628; Directorate Identifier 2016–NM–207–AD.

(a) Comments Due Date

We must receive comments by August 14, 2017.

(b) Affected ADs

This AD affects AD 2013–13–13, Amendment 39–17501 (79 FR 48957, August 19, 2014) (''AD 2013–13–13'').

(c) Applicability

This AD applies to all Airbus Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 05.

(e) Reason

This AD was prompted by a revision of certain airworthiness limitation items (ALI) documents, which require more restrictive maintenance requirements and airworthiness limitations. We are issuing this AD to prevent fatigue cracking, damage, or corrosion in principal structural elements, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Revision of Maintenance or Inspection Program

Within 3 months after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the information specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD. The initial compliance times for doing the tasks is at the time specified in the service information identified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, or within 3 months after the effective date of this AD, whichever occurs later.

(1) Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT—ALI),'' Revision 01, dated August 7, 2015.

(2) Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT—ALI),'' Variation 1.1, dated January 25, 2016.

(3) Airbus A310 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Variation 1.2, dated July 22, 2016.

(h) No Alternative Actions, and Intervals

After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), or intervals, may be used unless the actions and/or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(i) Terminating Action for AD 2013–13–13

Accomplishing the actions required by this AD terminates all requirements of AD 2013–13–13 for that airplane only.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–

116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016–0217, dated November 2, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0628.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com*. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 22, 2017.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–13755 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0629; Directorate Identifier 2016–NM–184–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This proposed AD was prompted by reports of fatigue cracking in the frame outboard chord and in the radius of the auxiliary chord at a certain area. This proposed AD would require inspections to detect this cracking, and corrective action if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 14, 2017.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0629.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0629; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6450; fax: (425) 917–6590; email: *alan.pohl@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–0629; Directorate Identifier 2016–NM–184–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports indicating that fatigue cracking was found in the frame outboard chord at BS 727 and in the radius of the auxiliary chord at BS 727 and S–18A on certain airplanes. Cracks in the outboard chord were found on airplanes having between 20,000 and 85,000 flight cycles, and between 27,000 and 74,000 flight hours. Cracks in the radius of the auxiliary chord were found on airplanes having between 46,000 and 85,000 flight cycles, and between 41,000 and 64,000 flight hours. The cracks were caused by fatigue, and, for certain airplanes, the fretting of adjacent parts contributed to the initiation of the fatigue damage. This condition, if not corrected, could result in reduced structural integrity of the outboard chord and consequent rapid decompression of the airplane.

Related Rulemaking

On October 16, 2012, we issued AD 2012–23–04, Amendment 39–17260 (77 FR 69747, November 21, 2012) (''AD 2012–23–04''), applicable to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. That AD requires various inspections for cracks in the outboard chord of the frame at BS 727. That AD also requires inspections for cracks in the BS 727 frame outboard chord and the radius of the auxiliary chord, for certain airplanes. That AD was prompted by several reports of fatigue cracking in the frame outboard chord at BS 727 and in the radius of the auxiliary chord. The actions required by that AD are intended to detect and correct fatigue cracking of the outboard and auxiliary chords, which could result in reduced structural integrity of the outboard chord and consequent rapid decompression of the airplane.

Since issuance of AD 2012–23–04, the FAA has found discrepancies in the requirements of that AD, as follows:

• The optional terminating action specified in paragraph (r) of AD 2012–23–04 allows terminating action if the preventive modification is installed. However, Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, allows terminating action only if both the BS 727 outboard chord is replaced and the preventive modification is installed. Consequently, for airplanes having line numbers 1 through 999 inclusive on which the preventive modification may have been installed, the outboard chord may not have been replaced. Additionally, paragraph (r)(2) of AD 2012–23–04 specifies replacing only a cracked outboard chord; however, the intent was to require replacement of the outboard chord whether it was cracked or not. In light of these factors, there could be cracking in the auxiliary chord combined with cracking in the outboard chord. This cracking could progress undetected and result in the identified unsafe condition.

• Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, contains instructions to determine whether the modification should be classified as interim or permanent; a one-time inspection is specified after the interim modification is done. The instructions specified in the previous service information did not contain this stipulation during installation of the preventive modification. Therefore, the modification could have resulted in edge margins in the frame outboard chord that would have been classified as interim had the modification been done in accordance with Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. Since neither Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, nor AD 2012–23–04 contained instructions to measure edge margins, it is possible that an edge margin condition exists, so the one-time follow-on inspection must be done.

• Paragraph (r) of AD 2012–23–04 terminates the one-time inspection specified in Part 8 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, for airplanes that have the interim preventive modification installed. This inspection is referenced in paragraph (o) of AD 2012–23–04, and should not have been terminated. Paragraph (o) of AD 2012–23–04 was incorrectly included in the list of paragraphs with inspections that are terminated after accomplishing paragraph (r) of that AD.

Therefore, since the discrepancies described previously provide inadvertent relief to operators, we find it necessary to issue additional, new AD rulemaking to provide additional inspection requirements. We have confirmed that the requirements of this AD correct those discrepancies and do not conflict with other requirements of AD 2012–23–04.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. The service information describes procedures for inspections for cracks of the BS 727 frame outboard chord and in the radius of the auxiliary chord, and repair or replacement if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

This AD corrects discrepancies in the requirements for certain airplanes identified in AD 2012–23–04. The FAA has considered that fact in determining whether to issue a new AD action or to supersede AD 2012–23–04. We have determined that a less burdensome approach is to issue a separate AD action applicable to the airplanes on which the discrepancies could have occurred. This proposed AD would not supersede AD 2012–23–04, and compliance with the requirements must continue for airplanes listed in the applicability of AD 2012–23–04. This proposed AD is a separate AD action, applicable only to the airplanes identified in paragraph (c) of this AD.

Costs of Compliance

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Affected airplanes of U.S. registry	Cost per product	Cost on U.S. operators
Detailed and High Frequency Eddy Current (HFEC) inspections.	6 work-hours × $85 per hour = $510 per inspection cycle.	5	$510	$2,550 per inspection cycle.
One-time follow-on HFEC inspection ..	9 work-hours × $85 per hour = $765 ..	5	765	$3,825.
HFEC inspection	9 work-hours × $85 per hour = $765 ..	150	765	$114,750.

We estimate the following costs to do any necessary repairs that would be required based on the results of the inspections. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair of cracking of the outboard chord frame	514 work-hours × $85 per hour = $43,690	$13,586	$57,276
Repair of cracking of the outboard chord	49 work-hours × $85 per hour = $4,165	4,255	8,420

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2017–0629; Directorate Identifier 2016–NM–184–AD.

(a) Comments Due Date

We must receive comments by August 14, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of fatigue cracking in the frame outboard chord and in the radius of the auxiliary chord at body station (BS) 727 and stringer (S) 18A. We are issuing this AD to detect and correct fatigue cracking of the outboard and auxiliary chords, which could result in reduced structural integrity of the outboard chord and consequent rapid decompression of the airplane.

(f) Compliance

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

(g) Repetitive Inspections and Corrective Action

For airplanes identified in paragraph (h) of this AD: Within 4,500 flight cycles or 24 months after the effective date of this AD, whichever occurs first, do internal detailed and High Frequency Eddy Current (HFEC) inspections to detect cracks in the auxiliary chord radius, in accordance with Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. If any crack is found during any inspection required by this paragraph, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD. Repeat the inspections thereafter at intervals not to exceed 15,000 flight cycles. Replacement of the outboard chord of the frame at BS 727 concurrently with the installation of the preventive modification of the outboard chord in accordance with Part 6 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, terminates the repetitive inspections required by this paragraph.

(h) Airplanes for Actions Specified in Paragraph (g) of This AD

The actions specified in paragraph (g) of this AD are required for airplanes that meet the criteria of paragraphs (h)(1), (h)(2), (h)(3), and (h)(4) of this AD.

(1) Model 737–100, –200, and –200C series airplanes, line numbers 1 through 999 inclusive.

(2) Airplanes identified as Groups 1, 2, and 3 in Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006.

(3) Airplanes on which a preventive modification has been installed in accordance with the method specified in paragraph (h)(3)(i), (h)(3)(ii), or (h)(3)(iii) of this AD.

(i) Part 6 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006.

(ii) Part II of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 1, dated May 25, 1995.

(iii) Part II of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, dated June 30, 1994.

(4) Airplanes on which the outboard chord has not been replaced in accordance with the method specified in paragraph (h)(4)(i), (h)(4)(ii), or (h)(4)(iii) of this AD.

(i) Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006.

(ii) Part I of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 1, dated May 25, 1995.

(iii) Part I of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, dated June 30, 1994.

(i) Edge Margin Measurement, Related Investigative Actions, and Repair

For Model 737–100, –200, and –200C series airplanes having line numbers 1 through 999 inclusive, identified as Groups 1 through 3 in Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, on which the preventive modification has been installed in accordance with Boeing Alert Service Bulletin 737–53A1166, dated June 30, 1994; or Boeing Alert Service Bulletin 737–53A1166, Revision 1, dated May 25, 1995: Within 60,000 flight cycles after accomplishing the preventive modification, determine if the modification is classified as interim or permanent by using the edge margin measurement and repair classification specified in Part 6 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. In lieu of measuring on the airplane, a review of engineering documentation may be used to classify the modification if the engineering documentation was completed at the time of the modification and has the edge margins recorded.

(1) If the modification is classified as permanent, no further action is required by paragraph (i) of this AD.

(2) If the modification is classified as interim: Within 60,000 flight cycles after accomplishment of the interim modification of the outboard chord of the frame at BS 727 at S–18A, but no earlier than 50,000 flight cycles after accomplishment of the modification, do a one-time follow-on open-hole eddy current inspection to detect cracks

in the modified chord, in accordance with Part 8 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. If any crack is found, before further flight, repair in accordance with Part 3 or Part 4, as applicable, of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006; except, if the repairs cannot be installed using the identified procedures, repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(j) Follow-On Inspection for Interim Modification and Repair

For airplanes having line numbers 1 through 3132 inclusive, on which an interim modification of the BS 727 outboard chord as defined in Part 6 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, has been accomplished: Within 60,000 flight cycles after accomplishment of the interim modification of the outboard chord of the frame at BS 727 at S–18A, but no earlier than 50,000 flight cycles after accomplishment of the modification, do a one-time follow-on open-hole eddy current inspection to detect cracks in the modified chord, in accordance with Part 8 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006. If any crack is found during the inspection required by this paragraph, before further flight, repair in accordance with Part 3 or Part 4, as applicable, of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006; except, where the repairs cannot be installed using the procedures identified in this service bulletin, repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(k) Exception to the Service Information

Access and restoration procedures specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1166, Revision 2, dated May 25, 2006, are not required by this AD. Operators may do those actions following their approved maintenance procedures.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(m) Related Information

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6450; fax: (425) 917–6590; email: *alan.pohl@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 22, 2017.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–13773 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0627; Directorate Identifier 2017–NM–037–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A330–200 Freighter, –200, and –300 series airplanes; and Airbus Model A340–200, –300, –500, and –600 series airplanes. This proposed AD was prompted by a report that the trimmable horizontal stabilizer actuator (THSA) might not function as intended after failure of the primary load path. This proposed AD would require repetitive detailed visual inspections for discrepancies of the THSA upper attachments and no-back housing. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 14, 2017.

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

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

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com*; Internet *http://www.airbus.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0627; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments

to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–0627; Directorate Identifier 2017–NM–037–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0044, dated March 9, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A330–200 Freighter, –200 and –300 series airplanes; and Airbus Model A340–200, –300, –500, and –600 series airplanes. The MCAI states:

> The Trimmable Horizontal Stabilizer Actuator (THSA), as installed on A330 and A340 aeroplanes, was initially designed to stall when engaging on the upper secondary load path (SLP) after primary load path (PLP) failure. Such stall triggers system monitoring detection. New mission profile analysis revealed that in some cases, the THSA could be operated while engaged on the upper SLP without stalling [*i.e.,* the THSA might not function as intended after failure of the primary load path]. The partial engagement of the SLP at upper attachment level does not trigger any indication to the flight crew.
>
> This condition, if not detected and corrected, could lead to THSA upper attachment failure and consequent disconnection of the THSA from the aeroplane structure, possibly resulting in loss of control of the aeroplane.
>
> For the reasons described above, this [EASA] AD requires repetitive detailed [visual] inspections (DET) of the upper THSA attachments parts and the PLP and SLP fuselage attachment points, and, depending on findings (which include, but are not limited to, failure of the primary load path), accomplishment of applicable [additional inspections for discrepancies and] corrective action(s).

The additional inspections include a detailed visual inspection for discrepancies of the upper attachment fitting of the airplane and a detailed visual inspection for discrepancies of the removed THSA. Corrective actions include repair and replacement of the THSA. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0627.

Related Service Information Under 1 CFR Part 51

We reviewed the following Airbus service information:

- Airbus Service Bulletin A330–27–3218, Revision 01, dated December 5, 2016.
- Airbus Service Bulletin A340–27–4203, Revision 01 dated December 5, 2016.
- Airbus Service Bulletin A340–27–5067, Revision 01 dated December 5, 2016.

The service information describes procedures for detailed visual inspections for discrepancies of the THSA upper attachments and no-back housing, additional inspections for discrepancies, and corrective actions. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 102 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	3 work-hours × $85 per hour = $255 per inspection cycle.	$0	$255 per inspection cycle	$26,010

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	20 work-hours × $85 per hour = $1,700	$734,661	$736,361

We have received no definitive data that would enable us to provide cost estimates for other on-condition actions specified in this proposed AD.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2017–0627; Directorate Identifier 2017–NM–037–AD.

(a) Comments Due Date

We must receive comments by August 14, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342 and –343 airplanes; and Airbus Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes; certificated in any category, all manufacturer's serial numbers.

(d) Subject

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

(e) Reason

This AD was prompted by a report that the trimmable horizontal stabilizer actuator (THSA) might not function as intended after failure of the primary load path. We are issuing this AD to detect and correct discrepancies of the THSA upper attachments and no-back housing, which could lead to THSA upper attachment failure and consequent disconnection of the THSA from the airplane structure, possibly resulting in loss of control of the airplane.

(f) Compliance

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

(g) Repetitive Detailed Visual Inspections

Before exceeding the Threshold in Table 1 to paragraph (g) of this AD, as applicable, or within 3 months after the effective date of this AD, whichever occurs later; and thereafter at intervals not to exceed the inspection interval values defined in Table 1 to paragraph (g) of this AD; accomplish a detailed visual inspection for discrepancies of the trimmable horizontal stabilizer actuator (THSA) upper attachments and no-back housing, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable. Where the ''Threshold'' column of table 1 to paragraph (g) of this AD specifies compliance times in ''FH'' (flight hours) or ''FC'' (flight cycles), those compliance times are flight hours or flight cycles since the first flight of the airplane, or since the last accomplishment of Airbus Model A330 or A340 Maintenance Review Board Report task 27.40.00/07, or since the last detailed visual inspection of the THSA done in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, A340–27–4203, or A340–27–5067, all dated July 1, 2016, as applicable.

TABLE 1 TO PARAGRAPH (g) OF THIS AD—THSA UPPER ATTACHMENTS/NO-BACK HOUSING INSPECTIONS

Affected airplanes	Compliance times (whichever occurs first, flight hours (FH) or flight cycles (FC))	
	Threshold	Inspection interval (not to exceed)
A330, A340–200 and A340–300	Before 4,000 FH or 1,000 FC	4,000 FH or 1,000 FC.
A340–500 and A340–600	Before 4,000 FH or 800 FC	4,000 FH or 800 FC.

(h) Additional Inspections and Corrective Actions

(1) If, during any inspection required by paragraph (g) of this AD, any discrepancy identified in the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable, is detected, before further flight, remove the THSA, and accomplish a detailed visual inspection for discrepancies of the upper attachment fitting of the airplane and a detailed visual inspection for discrepancies of the removed THSA, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable. As an alternative to the removed THSA inspections required by this paragraph, before further flight, replace the THSA with a serviceable part (as defined in paragraph (i) of this AD).

(2) If, during any inspection of the upper attachment fitting of the airplane required by paragraph (h)(1) of this AD, any discrepancy identified in the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable, is detected, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (k)(2) of this AD.

(3) If, during any inspection of the removed THSA required by paragraph (h)(1) of this AD, no discrepancy specified in the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable, is detected, before further flight, reinstall the THSA, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203,

Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable.

(4) If, during any inspection of the removed THSA required by paragraph (h)(1) of this AD, any discrepancy specified in the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable, is detected, before further flight, replace the THSA with a serviceable part (as defined in paragraph (i) of this AD), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable.

(i) Definition of Serviceable THSA

For the purpose of this AD, a serviceable THSA is a part that has accumulated less than 4,000 FH or 1,000 FC (for Airbus Model A330, A340–200, or A340–300 airplanes) or 4,000 FH or 800 FC (for Airbus Model A340–500 or A340–600 airplanes), whichever occurs first since the first flight of the airplane, or since the last overhaul of the THSA, or since the last detailed visual inspection of the THSA in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27–3218, Revision 01, A340–27–4203, Revision 01, or A340–27–5067, Revision 01, all dated December 5, 2016, as applicable.

(j) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g), (h)(1), (h)(3), and (h)(4) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD.

(1) Airbus Service Bulletin A330–27–3218, Revision 00, dated July 1, 2016.

(2) Airbus Service Bulletin A340–27–4203, Revision 00, dated July 1, 2016.

(3) Airbus Service Bulletin A340–27–5067, Revision 00, dated July, 1 2016.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Branch, send it to attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

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

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–044, dated March 9, 2017, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0627.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office–EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com*; Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 22, 2017.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–13780 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 417

Waiver of Flight Termination Receiver Qualification by Similarity Deficiencies

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of waiver.

SUMMARY: This notice concerns three petitions for waiver submitted to the FAA by Rocket Lab USA Inc. (RL) for the Flight Termination Receiver (FTR) Qualification by Similarity (QBS): A petition to waive the requirement that a component may be qualified based on similarity to a component that has already been qualified for use only if the environments encountered by the previously qualified component during its qualification or flight history were equal or more severe than the Rocket Lab qualification environments; a petition to waive the Electromagnetic Interference and Compatibility (EMI/EMC) on the same units; and a petition to waive the requirement that the same manufacturer must produce the qualified and the unqualified component in the same location using identical tools and manufacturing processes. The FAA grants these three petitions.

DATES: Issued in Washington, DC, on May 15, 2017.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this waiver, contact Michael Wiktowy, Licensing Program Lead, Commercial Space Transportation—Licensing and Evaluation Division, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–7287; email: *Michael.Wiktowy@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

RL submitted a petition to the FAA's Office of Commercial Space Transportation (AST) requesting relief from regulatory requirements for a launch license for flight of Electron test flight missions from Mahia, New Zealand. Specifically, RL requested relief from 14 CFR E417.7(f)(2) and (5), Qualification Testing and Analysis by Similarity for the Flight Termination Receiver. For Qualification, the Flight Termination Receiver is required to meet Table E417.19–2, which states with note (5): ''The same three sample components must undergo each test designated with an X. For a test designated with a quantity of less than three, each sample component tested must be one of the original three sample components.'' For Qualification Testing and Analysis by Similarity, Part 417 Appendix E section 417.7(f) provides the requirements a launch operator must satisfy in order to qualify or re-qualify a flight termination system component's design through qualification by similarity to tests performed on identical or similar hardware. Section E417.7(f)(2) states that to qualify component ''A'' based on similarity to

component ''B'', that has already been qualified for use, a launch operator must demonstrate that the environment encountered by ''B'' must have been equal to or more severe than the qualification environments required for ''A''. Specifically, RL used different components for the random vibration qualification test and the EMI/EMC qualification test instead of the original three qualification sample components used for the other tests under E417.7(f)(2). Section E417.7(f)(5) requires that the same manufacturer produce ''A'' and ''B'' in the same location using identical tools and manufacturing processes. Specifically, RL's sample ''A'' and ''B'' were manufactured at different locations with different manufacturing processes.

The FAA licenses the launch of a launch vehicle and reentry of a reentry vehicle under authority granted to the Secretary of Transportation in the Commercial Space Launch Act of 1984, as amended and re-codified by 51 U.S.C. Subtitle V, chapter 509 (Chapter 509), and delegated to the FAA Administrator and the Associate Administrator for Commercial Space Transportation, who exercises licensing authority under Chapter 509.

RL is a private commercial space flight company. RL seeks to lower the cost and increase the frequency of access to space for small payloads, potentially expanding the opportunity for space services and research. RL's petition for waiver addresses all upcoming Electron test flights that RL plans to launch from the Mahia Peninsula, New Zealand. The Electron launch is the first planned test flight from the privately-owned Rocket Lab Launch Complex at Mahia Peninsula in Hawkes Bay, New Zealand. The launch location is capable of hosting launches to the northeast, east, and south. The area within 20 NM surrounding the launch site is extremely remote, and has a low population density. The launch flight corridor will have minimal impact on air and marine traffic.

Waiver Criteria

Chapter 509 allows the FAA to waive a license requirement if the waiver (1) will not jeopardize public health and safety, safety of property; (2) will not jeopardize national security and foreign policy interests of the United States; and (3) will be in the public interest. See 51 U.S.C. 50905(b)(3) (2011); 14 CFR 404.5(b) (2011).

Section E417.7(f)(2) and (5) Waiver Petition

Section E417.7(f)(2) requires a launch operator wishing to qualify a component's design through qualification by similarity to tests performed on identical or similar hardware to demonstrate that the environments encountered by the component during its qualification or flight history were equal to or more severe than the qualification environments required for a component that has already been qualified for use. Section E417.7(f)(5) requires a launch operator qualifying a component's design as discussed above to demonstrate that the same manufacturer produced both the qualified component and the component the launch operator wishes to qualify in the same location using identical tools and manufacturing processes. For reasons described below, the FAA waives the requirements in section E417.7(f)(2) and (5) to allow RL to use components in its flight termination system that were qualified by similarity to more than one qualified component.

In deciding whether or not to issue a waiver, the FAA had to analyze whether the waiver: (1) Would jeopardize public health and safety or safety of property; (2) would jeopardize national security and foreign policy interests of the United States; and (3) was in the public interest. See 51 U.S.C. 50905(b)(3); 14 CFR 404.5(b).

i. Public Health and Safety and Safety of Property

Part 417 contains requirements for qualification and acceptance testing of flight termination system components based on the approach used at the federal launch ranges. At federal launch ranges, flight termination system components are tested according to federal range-approved test procedures and requirements. Verification methods include test, analysis, and inspection. As an alternative to testing, components of an FTS are sometimes qualified by similarity. A component that has been qualified through testing for one launch vehicle may be approved for use on a different launch vehicle if it can be shown that the environments in which it must operate on the second vehicle are no harsher than those of the first. Also, with limited additional testing, the component may be qualified for a more severe environment. Although RL did not complete each of the qualification by similarity requirements for its flight termination receiver as required by the regulations, the failsafe design of the Electron's flight termination system combined with the remoteness of the operating area allow the FAA to find that RL's activities will not jeopardize public health and safety and safety of property.

RL procured the Electron launch vehicle's flight termination receiver from Vendor A, who performed several qualification and delta qualification tests. A delta qualification test extends the tested environments to cover specific tests or levels that were not previously covered. RL submitted a Qualification by Similarity Analysis Report to the FAA, referencing three previous groups of similar flight termination receiver qualification and delta qualification tests performed by Vendor A. Group 1 was subjected to most of the qualification testing required by 14 CFR Table E417.19–2, with three exceptions: (a) Group 1 did not satisfy 14 CFR E417.7(f)(2) because the random vibration qualification environment encountered by Group 1 was not equal to or more severe than the random vibration qualification environment required for the Electron flight termination receivers, falling below for approximately 3.5% over the required 20 Hz to 2000 Hz test band; (b) Group 1 was not subjected to EMI/EMC testing; and (c) Group 1 did not meet the requirements of 14 CFR E417.7(f)(5) because it was not produced in the same manufacturing location using identical tools and manufacturing processes as the Rocket Lab Electron flight termination receivers. Group 1's deficiencies were mitigated by two subsequent delta qualification tests on 2 groups (referred to herein as Group 2 and Group 3) of similar receivers. Group 2 satisfied Electron's required random vibration qualification test levels for the entire required test band, and Group 2 was manufactured in the same location using identical tools and manufacturing processes as Electron flight termination receivers. Group 3 successfully passed EMI/EMC qualification testing.

Group 1 also did not meet the requirements of 14 CFR E417.7(f)(5) because Group 1 was not produced in the same manufacturing location using identical tools and manufacturing processes as Group 2 and Electron flight termination receivers. Vendor A originally outsourced one of the flight termination receiver's printed circuit boards to another supplier. In late 2013, Vendor A upgraded its internal equipment and process, and assembled the printed circuit boards in-house. Group 1 and Group 3 were manufactured and qualification tested before this change in equipment and process, whereas Group 2 and Electron's flight termination receivers were assembled after the change. To verify that the equipment and process change did not invalidate previous qualification and delta qualification testing, Vendor

A applied the same heritage process profile to the new equipment, retained heritage printed circuit board samples for periodic process control comparisons, and implemented periodic visual/x-ray inspections for consistency validation. Heritage and new equipment specifications were also assessed to compare their performance characteristics. White Sand Missile Range has reviewed and accepted this process change, for U.S. Government launch vehicle programs conducting launches from its launch range, based on improved reliability and quality of the process.

The FAA waives the requirements of E417.7(f)(2) and (5) because the Electron has implemented a failsafe flight safety system design that would terminate thrust to the vehicle should both flight termination receivers fail or communication was lost with the ground station, and RL's operating area is remote enough that were it to experience a catastrophic failure, it would not jeopardize public health and safety and safety of property. The Electron test flight missions would occur from the isolated Mahia Peninsula in New Zealand. The area within 20 NM of Mahia Peninsula has a very low population density. The Electron flight corridor is over the broad ocean area with minimal impact on air and marine traffic. Consequence analysis showed that less than 1 in 100,000 casualties would be expected if the worst foreseeable vehicle response mode (*i.e.,* where the vehicle guidance is assumed to fail in a manner that leads to an attempt to guide to erroneous, randomly located points) occurred at the worst flight time (relatively early in flight before the vehicle proceeds downrange) and the flight termination receiver failed to activate. Thus, the casualty expectation given the assumption of the worst possible failure would on average still produce significantly less casualties than the FAA's limit of 1 in 10,000, which does not assume failure but rather assigns realistic failure probabilities. Also, the flight termination receiver's failsafe feature will terminate thrust if there is a loss of power or Radio Frequency carrier or pilot tone signal, providing an additional safety margin. For these reasons, the FAA has determined that waiving sections E417.7(f)(2) and (5) for the Electron test flight missions from Mahia, New Zealand will not jeopardize public health and safety or safety of property.

ii. National Security and Foreign Policy Implications

The FAA has identified no national security or foreign policy implications associated with granting this waiver.

iii. Public Interest

The waiver is consistent with the public interest goals of Chapter 509 and the National Space Transportation Policy. Three of the public policy goals of Chapter 509 are: (1) To promote economic growth and entrepreneurial activity through use of the space environment; (2) to encourage the United States private sector to provide launch and reentry vehicles and associated services; and (3) to facilitate the strengthening and expansion of the United States space transportation infrastructure to support the full range of United States space-related activities. See 51 U.S.C. 50901(b)(1), (2), (4).

RL seeks to lower the cost and increase the frequency of access to space for small payloads, potentially expanding the opportunity for space services and research. These activities will help to make the U.S. launch industry more competitive internationally. The National Space Transportation Policy states that strengthening U.S. competitiveness in the international launch market and improving the cost effectiveness of U.S. space transportation services are in the public interest:

Maintaining an assured capability to meet United States Government needs, while also taking the necessary steps to strengthen U.S. competitiveness in the international commercial launch market, is important to ensuring that U.S. space transportation capabilities will be reliable, robust, safe, and affordable in the future. Among other steps, improving the cost effectiveness of U.S. space transportation services could help achieve this goal by allowing the United States Government to invest a greater share of its resources in other needs such as facilities modernization, technology advancement, scientific discovery, and national security. Further, a healthier, more competitive U.S. space transportation industry would facilitate new markets, encourage new industries, create high technology jobs, lead to greater economic growth and security, and would further the Nation's leadership role in space.

More specifically, Rocket Lab will be carrying onboard the Electron launch vehicle on its inaugural launch a flight test experiment for NASA Kennedy Space Center which will improve public risk mitigation capabilities from an errant launch vehicle. This component is designed and manufactured by NASA KSC and is part of the independent safety system which will be installed on the launch vehicles. This safety system will be capable of determining if the flight of the launch vehicle will pose an unacceptable increased risk to the public based on mission rules designed for its unique vehicle and flight characteristics and programmed into the safety system and terminate the flight of such launch vehicle. This type of capability is in public interest because this safety system will allow for improved protection of the public from mishaps resulting from flight of errant launch vehicles.

Issued in Washington, DC, on May 15, 2017.

Kenneth Wong,

Commercial Space Transportation, Licensing and Evaluation Division Manager.

[FR Doc. 2017–13567 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0257]

RIN 1625–AA09

Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating regulation that governs the DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ. This proposed regulation will allow the bridge to be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ, instead of being operated by an on-site bridge tender. This regulation will not change the operating schedule of the bridge.

DATES: Comments and related material must reach the Coast Guard on or before August 18, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0257 using Federal eRulemaking Portal at *http://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Hal R. Pitts, Fifth Coast Guard District (dpb); telephone (757) 398–6222, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose and Legal Basis

The DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ, owned and operated by Conrail Shared Assets, has a vertical clearance of 49 feet above mean high water in the closed-to-navigation position. There is a daily average of 28 New Jersey Transit trains and eight Conrail freight trains that cross the bridge and a daily average of three bridge openings that allow one or more vessels to transit through the bridge during each opening. The bridge is normally maintained in the closed position due to the average daily number of trains crossing the bridge. The operating schedule is published in 33 CFR 117.716. This current operating schedule has been in effect since 1984 and will not change with the implementation of remote operation of the bridge. However, within this proposed operating schedule, § 117.716 will be restructured from its current configuration to clearly distinguish the remote operation of the DELAIR Memorial Railroad Bridge. This proposed operating regulation allows the bridge to be operated remotely from the bridge owner's South Jersey dispatch center in Mount Laurel, NJ.

The Delaware River is used by a variety of vessels, including deep draft commercial vessels, tug and barge traffic, recreational vessels, and public vessels, including military vessels of various sizes. The three-year average number of bridge openings and maximum number of bridge openings by month and overall for 2013 through 2015, as drawn from the data contained in the bridge tender logs, is presented below.

Month	Average openings	Maximum openings
January	73	88
February	54	56
March	80	94
April	55	68
May	60	67
June	60	71
July	122	162
August	112	138
September	143	201
October	109	117
November	100	116
December	100	122
Monthly	89	201
Daily	3	7

The bridge owner and the maritime community have been working together since 2013 in an effort to incorporate sensors and other technologies into the bridge and the Conrail South Jersey dispatch center to allow for the safe and effective remote operation of the bridge.

On April 12, 2017, the Coast Guard published a temporary deviation entitled ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' in the **Federal Register** (82 FR 17561). This test deviation allows the bridge to be operated remotely from the bridge owner's South Jersey dispatch center in Mount Laurel, NJ. This test deviation is effective from 8 a.m. on April 24, 2017, to 7:59 a.m. on October 21, 2017.

III. Discussion of Proposed Rule

This proposed operating regulation will allow the bridge to be operated remotely from the bridge owner's South Jersey dispatch center in Mount Laurel, NJ. The remote operation system will include eight camera views (four marine and four rail), two forward-looking infrared equipped camera views (marine), marine radar, a dedicated telephone line for bridge operations, radio telephone on VHF–FM channels 13 and 16, and an automated identification system (AIS) transmitter to provide bridge status. The AIS transmitter has been installed on the New Jersey side of the bridge at the bridge and land intersection in approximate position 39°58′50.52″ N. (39.9807), 75°03′58.75″ W. (−75.06632). The AIS transmitter is assigned maritime mobile service identity (MMSI) number 993663001 and will provide the status of the bridge (open/closed/inoperative) via the name transmitted by the private aids to navigation as DELAIR BRG–OPEN (fully open and locked position, channel light green), DELAIR BRG–CLOSED (other than fully open, not inoperative), or DELAIR BRG–INOP (other than fully open, inoperative). The AIS transmitter will transmit the bridge status every two minutes and upon a change in the bridge status.

The remote operation system is designed to provide equal or greater capabilities compared to the on-site bridge tender in visibility of the waterway and bridge and in signals (communications) via sound and visual signals and radio telephone (voice) via VHF–FM channels 13 and 16. The remote operation system also incorporates real-time bridge status via AIS signal to aid mariners in voyage planning and navigational decision-making, a dedicated telephone line (856) 231–2301 for bridge operations, and push-to-talk (PTT) capability on VHF–FM channel 13.

The signals for the remote operation center or on-site bridge tender to respond to a sound signal for a bridge opening will include: (1) When the draw can be opened immediately—a sound signal of one prolonged blast followed by one short blast and illumination of a fixed white light not more than 30 seconds after the requesting signal, and (2) when the draw cannot be opened immediately—five short blasts sounded in rapid succession and illumination of a fixed red light not more 30 seconds after the vessel's opening signal. The signals for the remote operation center or on-site

bridge tender to respond to a visual signal for a bridge opening will include: (1) When the draw can be opened immediately—illumination of a fixed white light not more than 30 seconds after the requesting signal, and (2) when the draw cannot be opened immediately—illumination of a fixed red light not more than 30 seconds after the vessel's opening signal. The fixed white light will remain illuminated until the bridge reaches the fully open position. The fixed white and red lights will be positioned on the east (New Jersey) bridge abutment adjacent to the navigation span.

Vessels that require an opening shall continue to request an opening via the methods defined in 33 CFR 117.15(b) through (d) (sound or visual signals or radio telephone (VHF–FM) voice communications), via telephone at (856) 231–2301, or via push-to-talk (PTT) on VHF–FM channel 13. Vessels may push the PTT button five times while on VHF–FM channel 13 to request an opening.

The remote operation system will be considered in a failed condition and qualified personnel will return and operate the bridge within 60 minutes if any of the following conditions are found: (1) The remote operation system becomes incapable of safely and effectively operating the bridge from the remote operation center, (2) visibility of the waterway or bridge is degraded to less than equal that of an on-site bridge tender (all eight camera views are required), (3) signals (communications) via sound or visual signals or radio telephone (voice) via VHF–FM channels 13 or 16 become inoperative, or (4) AIS becomes inoperative.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The determination that this NPRM is not a significant regulatory action is based on the findings that: (1) Vessels will continue to transit the bridge in accordance with 33 CFR 117.716, (2) the remote operation system is designed to provide equal or greater capabilities compared to the on-site bridge tender, and (3) the bridge owner will be capable of restoring on-site operation of the bridge within 60 minutes if the remote operation system fails.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. There are no known adverse impacts to any entities related to this proposed rule, given no aspects of the remote operating system for the bridge will create any burdens on any entity as described in section IV.A above. The incorporation of the automated identification system (AIS) capability into the remote operation system is expected to aid mariners who have AIS capability or access to computer-based AIS data in safely navigating through the bridge by providing real-time bridge status.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies, and how, and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

D. Federalism and Indian Tribal Government

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

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of

actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. Normally, such actions are categorically excluded from further review under figure 2–1, paragraph (32)(e), of the Instruction.

A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this notice of proposed rulemaking and all public comments are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.716 to read as follows:

§117.716 Delaware River.

(a) The following apply to all drawbridges across the Delaware River:

(1) The draws of railroad bridges need not be opened when there is a train in the bridge block approaching the bridge with the intention of crossing or within five minutes of the known time of the passage of a scheduled passenger train.

(2) The opening of a bridge may not be delayed more than five minutes for a highway bridge or 10 minutes for a railroad bridge after the signal to open is given.

(3) The owners of drawbridges shall provide and keep in good legible condition two board gages painted white with black figures not less than six inches high to indicate the vertical clearance under the closed draw at all stages of the tide. The gages shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream.

(b) The draw of the Conrail Memorial Railroad Bridge, mile 104.6, at Pennsauken Township, NJ shall be operated as follows:

(1) The bridge will be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ unless the remote operation system is in a failed condition.

(2) An AIS transmitter has been installed on the New Jersey side of the bridge at the bridge and land intersection in approximate position 39°58′50.52″ N. (39.9807), 75°03′58.75″ (-75.06632). The AIS transmitter is assigned maritime mobile service identity (MMSI) number 993663001. The status of the bridge (open/closed/inoperative) will be provided via the name transmitted by the AIS private aids to navigation as DELAIR BRG–OPEN (fully open and locked position, channel light green), DELAIR BRG–CLOSED (other than fully open, not inoperative), or DELAIR BRG–INOP (other than fully open, inoperative). The AIS transmitter will transmit the bridge status every two minutes and upon a change in the bridge status.

(3) The remote operation system will be considered in a failed condition and qualified personnel will return and operate the bridge within 60 minutes if any of the following conditions are found:

(i) The remote operation system becomes incapable of safely and effectively operating the bridge from the remote operation center; or

(ii) Visibility of the waterway or bridge is degraded to less than equal that of an on-site bridge tender; or

(iii) Signals (communications) via sound or visual signals or radio telephone (voice) via VHF–FM channels 13 or 16 become inoperative; or

(iv) AIS becomes inoperative.

(4) Vessels that require an opening shall continue to request an opening via the methods defined in § 117.15(b) through (d) (sound or visual signals or radio telephone (VHF–FM) voice communications), via telephone at (856) 231–2301, or via push-to-talk (PTT) on VHF–FM channel 13. Vessels may push the PTT button five times while on VHF–FM channel 13 to request an opening.

(5) The signals for the remote operation center or on-site bridge tender to respond to a sound signal for a bridge opening include:

(i) When the draw can be opened immediately—a sound signal of one prolonged blast followed by one short blast and illumination of a fixed white light not more than 30 seconds after the requesting signal; or

(ii) When the draw cannot be opened immediately—five short blasts sounded in rapid succession and illumination of a fixed red light not more 30 seconds after the vessel's opening signal.

(6) The signals for the remote operation center or on-site bridge tender to respond to a visual signal for a bridge opening include:

(i) When the draw can be opened immediately—illumination of a fixed white light not more than 30 seconds after the requesting signal; or

(ii) When the draw cannot be opened immediately—illumination of a fixed red light not more 30 seconds after the vessel's opening signal.

(7) The fixed white light will remain illuminated until the bridge reaches the fully open position. The fixed white and red lights will be positioned on the east (New Jersey) bridge abutment adjacent to the navigation span.

Dated: June 19, 2017.

M.L. Austin,

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

[FR Doc. 2017–13857 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2017–10]

Exemptions To Permit Circumvention of Access Controls on Copyrighted Works

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of inquiry and request for petitions.

SUMMARY: The United States Copyright Office is initiating the seventh triennial rulemaking proceeding under the Digital Millennium Copyright Act (''DMCA''), concerning possible temporary exemptions to the DMCA's prohibition against circumvention of technological measures that control access to copyrighted works. In this proceeding, the Copyright Office is establishing a new, streamlined procedure for the renewal of exemptions that were granted during the sixth triennial rulemaking. If renewed, those current exemptions would remain in force for an additional three-year period (October 2018—October 2021). Members of the public seeking the renewal of current exemptions should submit petitions as described below; parties opposing such renewal will then have the opportunity to file comments in response. The Office is also accepting petitions for *new* exemptions to engage in activities not currently permitted by existing exemptions, which may include proposals that expand upon a current exemption. Those petitions, and any renewal petitions that are meaningfully opposed, will be considered pursuant to a more comprehensive rulemaking process similar to that used for the sixth rulemaking (*i.e.,* three rounds of written comment, followed by public hearings).

DATES: Written petitions for renewal of current exemptions must be received no later than 11:59 p.m. Eastern Time on July 31, 2017. Written comments in response to any petitions for renewal must be received no later than 11:59 p.m. Eastern Time on September 13, 2017. Written petitions for new exemptions must be received no later than 11:59 p.m. Eastern Time on September 13, 2017.

ADDRESSES: Written petitions for renewal of current exemptions must be completed using the form provided on the Office's Web site at *https://www.copyright.gov/1201/2018/renewal-petition.pdf.* Written petitions proposing new exemptions must be completed using the form provided on the Office's Web site at *https://www.copyright.gov/1201/2018/new-petition.pdf.* The Copyright Office is using the regulations.gov system for the submission and posting of public petitions and comments in this proceeding. All petitions and comments are therefore to be submitted electronically through *regulations.gov*. Specific instructions for submitting petitions and comments are available on the Copyright Office Web site at *https://www.copyright.gov/1201/2018.* If electronic submission is not feasible, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, Deputy General Counsel, by email at *resm@loc.gov,* Anna Chauvet, Assistant General Counsel, by email at *achau@loc.gov,* or Jason E. Sloan, Attorney-Advisor, by email at *jslo@loc.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. The Digital Millennium Copyright Act and Section 1201

The Digital Millennium Copyright Act (''DMCA'') [1] has played a pivotal role in the development of the modern digital economy. Enacted by Congress in 1998 to implement the United States' obligations under two international treaties,[2] the DMCA was intended to foster the growth and development of a thriving, innovative, and flexible digital marketplace by making digital networks safe places to disseminate and use copyrighted materials.[3] It did this by, among other things, ensuring adequate legal protections for copyrighted content to ''support new ways of disseminating copyrighted materials to users, and to safeguard the availability of legitimate uses of those materials by individuals.'' [4]

These protections, codified in section 1201 of title 17, United States Code, as envisioned by Congress, seek to balance the interests of copyright owners and users, including the personal interests of consumers, in the digital environment.[5] Section 1201 does this by protecting the use of technological measures (also called technological protection measures or TPMs) used by copyright owners to prevent unauthorized access to or use of their works.[6] Section 1201 contains three separate protections for TPMs. First, it prohibits circumvention of technological measures employed by or on behalf of copyright owners to protect access to their works (also known as access controls). Access controls include, for example, a password requirement limiting access to a Web site to paying customers, or authentication codes in video game consoles to prevent the playing of pirated copies. Second, the statute prohibits trafficking in devices or services primarily designed to circumvent access controls. Finally, it prohibits trafficking in devices or services primarily designed to circumvent TPMs used to protect the copyright rights of the owner of a work (also known as copy controls). Copy controls protect against unauthorized uses of a copyrighted work once access has been lawfully obtained. They include, for example, technology preventing the copying of an e-book after it has been downloaded to a user's device. Because title 17 already forbids copyright infringement, there is no corresponding ban on the act of circumventing a copy control.[7] These prohibitions supplement the preexisting rights of copyright owners under the Copyright Act of 1976 by establishing separate and distinct causes of action independent of any infringement of copyright.[8]

At the same time, section 1201 contains a number of discrete, statutory exemptions to these prohibitions, to avoid curtailing legitimate activities such as security testing, law enforcement activities, or the protection of personally identifying information.[9] In addition, to accommodate changing marketplace realities and ensure that access to copyrighted works for lawful

[1] Public Law 105–304, 112 Stat. 2860 (1998).

[2] WIPO Copyright Treaty, Dec. 20, 1996, 36 I.L.M. 65 (1997); WIPO Performances and Phonograms Treaty, Dec. 20, 1996, 36 I.L.M. 76 (1997).

[3] *See* Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4th, 1998, at 2, 6 (Comm. Print 1998) (''House Manager's Report''); H.R. Rep. No. 105–551, pt. 2, at 21, 23 (1998); H.R. Rep. No. 105–551, pt. 1, at 10 (1998); S. Rep. No. 105–190, at 1–2, 8–9 (1998).

[4] House Manager's Report at 6.

[5] *See* H.R. Rep. No. 105–551, pt. 2, at 26.

[6] 17 U.S.C. 1201(a)–(b).

[7] S. Rep. No. 105–190, at 12.

[8] U.S. Copyright Office, Section 1201 of Title 17, at i, iii, 43–45 (June 2017), *https://www.copyright.gov/policy/1201/section-1201-full-report.pdf* (''Section 1201 Study'').

[9] 17 U.S.C. 1201(d)–(j).

purposes is not unjustifiably diminished,[10] the statute provides for a rulemaking proceeding whereby additional, temporary exemptions to the prohibition on circumventing access controls may be adopted by the Librarian of Congress, upon the recommendation of the Register of Copyrights in consultation with the Assistant Secretary for Communications and Information of the Department of Commerce.[11] In contrast to the permanent exemptions set out by statute, exemptions adopted pursuant to the rulemaking must be reconsidered every three years.[12] By statute, the triennial rulemaking process only addresses section 1201(a)(1)(A)'s prohibition on circumvention; the statute does not grant the authority to adopt exemptions to the anti-trafficking provisions of sections 1201(a)(2) or 1201(b).[13]

In order for a temporary exemption from the prohibition on circumvention to be granted through the triennial rulemaking, it must be established that ''persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition . . . in their ability to make noninfringing uses under [title 17] of a particular class of copyrighted works.'' [14] In evaluating the evidence, the statutory factors listed in section 1201(a)(1)(C) are weighed: ''(i) the availability for use of copyrighted works; (ii) the availability for use of works for nonprofit archival, preservation, and educational purposes; (iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and (v) such other factors as the Librarian considers appropriate.'' [15] To assess whether the implementation of access controls impairs the ability of individuals to make noninfringing uses of copyrighted works, the Office solicits proposals from the public and develops a comprehensive administrative record using information submitted by interested parties, and the Register makes a recommendation to the Librarian concerning whether exemptions are warranted based on that record.

II. Overview of the Rulemaking Process

The rulemaking process for the seventh triennial proceeding will be generally similar to the process introduced in the sixth proceeding. The primary change from the last rulemaking is the addition of a new streamlined procedure through which members of the public may petition for current temporary exemptions that were granted during the sixth triennial rulemaking to remain in force for an additional three-year period (October 2018–October 2021).

With this notice of inquiry, the Copyright Office is initiating the petition phase of the rulemaking, calling for the public to submit petitions both to renew current exemptions, as well as any comments in support of or opposition to such petitions, and to propose new exemptions. This two-track petition process is described below. After the close of the petition phase, the Office will publish a notice of proposed rulemaking (''NPRM'') to initiate the next phase of the rulemaking process, as described below.

Video tutorials explaining section 1201 in general and the rulemaking process can be found on the Office's 1201 rulemaking Web page at *https://www.copyright.gov/1201.*

III. Process for Seeking Renewal of Current Exemptions

A. Background

The Copyright Office recently published a comprehensive study of section 1201, including the process for adopting temporary exemptions. As part of the study, the Office solicited comments from the public and held roundtable discussions on whether the Office should adjust the rulemaking procedure to streamline the process for recommending readoption of previously adopted exemptions to the Librarian.[16] Previously, the Office had ''require[d] that a factual record to support an exemption be developed *de novo* each rulemaking,'' meaning rulemaking participants could not merely rely on previously submitted evidence from prior proceedings, but had to provide new evidence every three years.[17]

During the course of the study, a broad consensus of stakeholders requested that the Copyright Office change this approach and take steps within its regulatory authority to streamline the process for recommending the renewal of previously adopted exemptions to the Librarian.[18] In the study, the Office concluded as a threshold matter that ''the statute itself requires that exemptions cannot be renewed automatically, presumptively, or otherwise, without a fresh determination concerning the next three-year period. . . . [A] determination must be made specifically for each triennial period.'' [19] The Office further determined, however, that ''the statutory language appears to be broad enough to permit determinations to be based upon evidence drawn from prior proceedings, but only upon a conclusion that this evidence remains reliable to support granting an exemption in the current proceeding.'' [20] The Office elaborated:

> Adopting an approach of *de novo* assessment of evidence—compared to *de novo* submission—would allow future rulemakings to consider the appropriate weight to afford to previously submitted evidence when evaluating renewal requests. The relatively quick three-year turnover of the exemptions was put in place by Congress to allow the rulemaking to be fully considered and fairly decided on the basis of real marketplace developments, and any streamlined process for recommending renewed exemptions must retain flexibility to accommodate changes in the marketplace that affect the required rulemaking analysis. But at the same time, where there is little evidence of marketplace or technological changes, the Office believes it is statutorily permissible to establish a framework that expedites the recommendation to renew perennially sought exemptions.[21]

While the study concluded that the Office has some regulatory flexibility as to how it could implement a streamlined process for evaluating exemption renewals, it announced that the Office intended to implement such a process for this seventh triennial rulemaking proceeding. As promised in the study, below the Office provides further details regarding the streamlined process.[22]

B. Petitioning To Renew a Current Exemption

Those seeking readoption of a current exemption, granted during the sixth rulemaking, may petition for renewal by submitting the Copyright Office's required fillable form, available on the Office's Web site at *https://www.copyright.gov/1201/2018/renewal-petition.pdf.* This form is for renewal petitions only. The Office has a separate

[10] H.R. Rep. No. 105–551, pt. 2, at 35–36.

[11] 17 U.S.C. 1201(a)(1)(C); *see also id.* 1201(a)(1)(B)–(D).

[12] *Id.* 1201(a)(1)(C).

[13] *Id.* 1201(a)(1)(C), (a)(1)(E).

[14] *Id.* 1201(a)(1)(C).

[15] *Id.*

[16] 80 FR 81369, 81373 (Dec. 29, 2015); 81 FR 17206, 17206 (Mar. 28, 2016).

[17] Section 1201 Study at 130; *see id.* at 26–27.

[18] *Id.* at 127–28.

[19] *Id.* at 142.

[20] *Id.* at 143.

[21] *Id.* (internal quotation marks omitted).

[22] *Id.*

form, discussed below, for petitions for new exemptions.

Scope of Renewal. Renewal may only be sought for current exemptions as they are currently formulated, without modification. This means that if a proponent seeks to engage in any activities not currently permitted by an existing exemption, a petition for a *new* exemption must be submitted. Where a petitioner seeks to engage in activities that expand upon a current exemption, the Office recommends that the petitioner submit both a petition to renew the current exemption, and, separately, a petition for a new exemption. In such cases, the petition for a new exemption need only discuss those issues relevant to the proposed expansion of the current exemption. If the Office recommends readoption of the current exemption, then only those discrete aspects relevant to the expansion will be subject to the more comprehensive rulemaking procedure described below.

Automatic Reconsideration. If the Office declines to recommend renewal of a current exemption (as discussed below), the petition to renew will automatically be treated as a petition for a new exemption, and will be considered pursuant to the more comprehensive rulemaking proceeding. If a proponent has petitioned both for renewal and an expansion, and the Office declines to recommend renewal, the entire exemption (*i.e.,* the current exemption along with the proposed expansion) will automatically be considered under the more comprehensive public proceeding.

Petition Form and Contents. The petition to renew is a short form designed to let proponents identify themselves and the relevant exemption, and to make certain sworn statements to the Copyright Office concerning the existence of a continuing need and justification for the exemption. Use of the Office's prepared form is mandatory, and petitioners must follow the instructions contained in this notice and on the petition form. A separate petition form must be submitted for each current exemption for which renewal is sought. This is required for reasons of administrability and so that the basis for renewal set forth in each petition is clear as to which exemption it applies. While a single petition may not encompass more than one current exemption, the same party may submit multiple petitions.

The petition form has four components:

1. Petitioner identity and contact information. The form asks for each petitioner (*i.e.,* the individual or entity seeking renewal) to provide its name and the name of its representative, if any, along with contact information. Any member of the public capable of making the sworn declaration discussed below may submit a petition for renewal, regardless of prior involvement with past rulemakings. Petitioners and/or their representatives should be reachable through the provided contact information for the duration of the rulemaking proceeding. Multiple petitioning parties may jointly file a single petition.

2. Identification of the current exemption that is the subject of the petition. The form lists all current exemptions granted during the last rulemaking (codified at 37 CFR 201.40), with a check box next to each. The exemption for which renewal is sought is to be identified by marking the appropriate checkbox.

3. Explanation of need for renewal. The petitioner must provide a brief explanation summarizing the basis for claiming a continuing need and justification for the exemption. The required showing is meant to be minimal. The Office anticipates that petitioners will provide a paragraph or two detailing this information, but there is no page limit. While it is permissible to attach supporting documentary evidence as exhibits to the petition, it is not necessary. The Office's petition form includes an example of what it regards as a sufficient explanation.

4. Declaration and signature. One of the petitioners named in the petition must sign a declaration attesting to the continued need for the exemption and the truth of the explanation provided in support. Where the petitioner is an entity, the declaration must be signed by an individual at the organization having appropriate personal knowledge to make the declaration. The declaration may be signed electronically.

For the attestation to be trustworthy and reliable, it is important that the petitioner make it based on his or her own personal knowledge and experience. This requirement should not be burdensome, as a broad range of individuals have a sufficient level of knowledge and experience. For example, a blind individual having difficulty finding and purchasing e-books with appropriate assistive technologies would have such personal knowledge and experience to make the declaration with regard to the assistive technology exemption; so would a relevant employee or volunteer at an organization like the American Foundation for the Blind, which advocates for the blind, visually impaired, and print disabled, is familiar with the needs of the community, and is well-versed specifically in the e-book accessibility issue. It would be improper, however, for a general member of the public to petition for renewal if he or she knows nothing more about matters concerning e-book accessibility other than what he or she might have read in a brief newspaper article, or simply opposes the use of digital rights management tools as a matter of general principle.

The declaration also requires affirmation that, to the best of the petitioner's knowledge, there has not been any material change in the facts, law, or other circumstances set forth in the prior rulemaking record (available at *https://www.copyright.gov/1201/2015*) that originally demonstrated the need for the selected exemption, such that renewal of the exemption would not be justified. By ''material change,'' the Office means such significant change in the underlying conditions that originally justified the exemption when it was first granted, such that the appropriateness of continuing the exemption for another three years based on that original justification is called into question. This attestation tells the Office that the prior rulemaking record from when the current exemption was originally granted is still ripe and applicable in considering whether or not the same exemption is appropriate for the subsequent triennial period. Only after finding the old record to still be germane can the Office rely upon it in deciding, pursuant to 17 U.S.C. 1201(a)(1)(C), whether to recommend renewal.

C. Comments in Response to a Petition To Renew an Exemption

Any interested party may respond to a petition to renew a current exemption by submitting comments. While the primary purpose of these comments is to allow for opposition to renewing the exemption, comments in support of renewal are also permitted. Although no form is being provided for such comments, the first page of any responsive comments must clearly identify which exemption's readoption is being supported or opposed. While participants may comment on more than one exemption, a single submission may not address more than one exemption. For example, a party that wishes to oppose the renewal of both the wireless device unlocking exemption and the jailbreaking exemption must file separate comments for each.[23] The

[23] Commenters may, however, respond to multiple *petitions* to renew the same exemption in a single submission. For instance, if the Office

Office acknowledges that this format may require some parties to repeat certain general information (*e.g.,* about their organization) across multiple submissions, but the Office believes that the administrative benefits of creating self-contained, separate records for each exemption will be worth the modest amount of added effort involved.

Opposition to a renewal petition must be meaningful, such that, from the evidence provided, it would be reasonable for the Register to conclude that the prior rulemaking record and any further information provided in the renewal petition are insufficient to support recommending renewal of an exemption. For example, a change in case law might affect whether a particular use is noninfringing, new technological developments might affect the availability for use of copyrighted works, or new business models might affect the market for or value of copyrighted works. Such evidence could cause the Office to conclude that the prior evidentiary record is too stale to rely upon for an assessment affecting the subsequent three-year period. The Office may also consider whether opposition is meaningful only as to part of a current exemption.

Unsupported conclusory opinion and speculation will not be enough for the Register to refuse to recommend renewing an exemption she would have otherwise recommended in the absence of any opposition, or subject consideration of this exemption to the more comprehensive rulemaking procedure.

IV. Process for Seeking New Exemptions

Those seeking to engage in activities not currently permitted by an existing exemption, including activities that expand upon a current exemption, may propose a new exemption by filing a petition using the Copyright Office's required fillable form, available on the Office's Web site at *https://www.copyright.gov/1201/2018/new-petition.pdf.* Use of the Office's prepared form is mandatory, and petitioners must follow the instructions contained in this notice and on the petition form. As in the sixth rulemaking, a separate petition must be filed for *each* proposed exemption. The Office anticipates that it will, once again, receive a significant number of submissions, and requiring separate submissions for each proposed exemption will help both participants and the Office keep better track of the record for each proposed exemption. Although a single petition may not encompass more than one proposed exemption, the same party may submit multiple petitions.

The petition form has two components:

1. Petitioner identity and contact information. The form asks for each petitioner (*i.e.,* the individual or entity proposing the exemption) to provide its name and the name of its representative, if any, along with contact information. Petitioners and/or their representatives should be reachable through the provided contact information for the duration of the rulemaking proceeding. Multiple petitioning parties may jointly file a single petition.

2. Description of the proposed exemption. At this stage, the Office is only asking petitioners to briefly explain the nature of the proposed new or expanded exemption. The information that would be most helpful to the Office includes the following, to the extent relevant: (1) The types of copyrighted works that need to be accessed; (2) the physical media or devices on which the works are stored or the services through which the works are accessed; (3) the purposes for which the works need to be accessed; (4) the types of users who want access; and (5) the barriers that currently exist or which are likely to exist in the near future preventing these users from obtaining access to the relevant copyrighted works.

To be clear, petitioners need not propose precise regulatory language or fully define the contours of an exemption class in the petition. A short, plain statement describing the nature of the activities the petitioners wish to engage in will be sufficient. Although there is no page limit, the Office anticipates that petitioners will be able to adequately describe in plain terms the relevant information in a few sentences. The Office's petition form includes examples of what it regards as a sufficient description of a requested exemption.

Nor does the Office intend for petitioners to deliver the complete legal and evidentiary basis for their proposals in the petition, and specifically requests that petitioners not do so. Rather, the sole purpose of the petition is to provide the Office with basic information about the uses of copyrighted works that are adversely affected by the prohibition on circumvention. The Office will then use that information to itself formulate categories of potential exemptions, and group similar proposals into those categories, for purposes of the next, more substantive, phase of the rulemaking beginning with the publication of the NPRM.

Indeed, as during the last rulemaking, even the NPRM will not ''put forward precise regulatory language for the proposed classes, because any specific language for exemptions that the Register ultimately recommends to the Librarian will necessarily depend on the full record developed during this rulemaking.'' [24] Rather, the proposed categories of exemptions described in the NPRM will ''represent only a starting point for further consideration in the rulemaking proceeding, and will be subject to further refinement based on the record.'' [25] Thus, proponents will have the opportunity to further refine or expound upon their initial petitions during later phases of the rulemaking.

V. Notice of Proposed Rulemaking

Following receipt of all petitions, as well as comments on petitions for renewal, the Office will evaluate the material received and will issue an NPRM addressing all of the potential exemptions to be considered in the seventh rulemaking.

The NPRM will set forth which exemptions the Register will recommend for readoption, along with proposed regulatory language. The NPRM will also identify any exemptions the Register has declined to recommend for renewal under the streamlined process, after considering any opposition received. Those exemptions will instead be subject to the more comprehensive rulemaking procedure in order to build out the administrative record. The Register will not at the NPRM stage make a final determination to reject recommendation of any exemption that meets the threshold requirements of section 1201(a).[26]

For current exemptions for which renewal was sought but which were not recommended for readoption through the streamlined process and all new exemptions, including proposals to expand current exemptions, the NPRM will group them appropriately, describe them, and initiate at least three rounds of public comment. As with the sixth rulemaking, the Office plans to

receives six petitions in favor of readopting the current wireless device unlocking exemption, a commenter can file a single comment that addresses points made in the six petitions. That comment, however, may not address petitions to readopt the jailbreaking exemption.

[24] 79 FR 73856, 73859 (Dec. 12, 2014).

[25] *Id.* (internal quotation marks and citation omitted).

[26] *See* 79 FR 55687, 55692 (Sept. 17, 2014) (explaining that part of the purpose of providing the information in the petition phase is so the Office can ''confirm that the threshold requirements of section 1201(a) can be met''); *see also* 79 FR at 73859 (noting that three petitions sought an exemption which could not be granted as a matter of law and declining to put them forward for comment).

consolidate or group related and/or overlapping proposed exemptions where possible to simplify the rulemaking process and encourage joint participation among parties with common interests (though such collaboration is not required). As in previous rulemakings, the exemptions as described in the NPRM will represent only a starting point for further consideration in the rulemaking proceeding, and will be subject to further refinement based on the record. The NPRM will provide guidance regarding specific areas of legal and factual interest for the Office with respect to each proposed exemption, and suggest particular types of evidence that participants may wish to submit for the record. It will also contain additional instructions and requirements for submitting comments and will detail the later phases of the rulemaking proceeding—*i.e.,* public hearings, post-hearing questions, recommendation, and final rule—which will be similar to those of the sixth rulemaking.

As noted in the Office's study, however, the Office intends to issue the NPRM at an earlier point than during the sixth rulemaking proceeding, to give all parties sufficient time to participate in the process. Publishing the NPRM earlier should better accommodate the academic calendar and allow for greater law student participation during the more substantive comment and public hearing phases of the proceeding—something many commenters suggested during the study.[27] In addition, the Office will look for opportunities to preview regulatory language or ask additional post-hearing questions, where necessary to ensure sufficient stakeholder participation.[28]

[27] *See, e.g.,* Section 1201 Study Initial Reply Comments of International Documentary Association et al. at 3–4 (Apr. 1, 2016); Section 1201 Study Hearing Tr. at 132:10–133:17 (May 25, 2016) (McClure, American Foundation for the Blind); Section 1201 Study Hearing Tr. at 133:16–135:02 (May 19, 2016) (Decherney, University of Pennsylvania); Section 1201 Study Hearing Tr. at 108:13–109:05 (May 25, 2016) (Metalitz, Association of American Publishers, Motion Picture Association of America, Inc., & Recording Industry Association of America); Section 1201 Study Additional Comments of American Association of Law Libraries at 3 (Oct. 27, 2016). Given the statutory deadline, it was necessary to also move up the petition phase to align the written comment and hearing phases with the academic calendar. The Office determined this to be the most optimal choice, particularly given that the petitions are meant to be simple and short filings, as discussed above. Nevertheless, after discussing the schedule with a number of academic clinics, we selected a longer period for the filing of initial petitions to better accommodate academic schedules.

[28] Section 1201 Study at 150–51.

Dated: June 27, 2017.

Sarang V. Damle,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2017–13815 Filed 6–29–17; 8:45 am]

BILLING CODE 1410–30–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2017–7; Order No. 3982]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to an analytical method for use in periodic reporting (Proposal Three). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 16, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On June 22, 2017, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting the Commission to initiate an informal rulemaking proceeding to consider proposed changes to an analytical method related to periodic reports.[1] The Petition identifies the proposed analytical method changes filed in this docket as Proposal Three.

II. Proposal Three

Background. The Postal Service currently uses statistical estimates in the Revenue, Pieces, and Weight (RPW) Report for mailpieces reported in the Retail Systems Software Business Partners (RSS BP) application and bearing contract postal unit metered postage. Petition at 1. The RSS BP is the electronic point-of-sale management system that the Postal Service provides to contract postal units. *Id.* at 4. The statistical estimates used in the RSS BP management system are produced by the Postal Service's Origin-Destination Information System—Revenue, Pieces, and Weight (ODIS–RPW) probability-based sampling system. *Id.* at 4, 5.

Proposal. Proposal Three would change the methodology for measuring the national totals of revenue, pieces, and weight in the RPW Report for RSS BP mailpieces by replacing ODIS–RPW statistical sampling estimates with corresponding census data reported in the Postal Service's Retail Data Mart reporting system. *Id.* at 6. In support of Proposal Three, the Postal Service cites other proposals approved by the Commission which have replaced statistical estimates with census data. *See id.* at 3.

Rationale and impact. The Postal Service states that the proposed change in methodology ''provides a complete census source of transactional-level data of all RSS BP mailpieces and extra services.'' *Id.* at 6. The Postal Service asserts that the use of census data would lead one to expect equal or improved data quality because census data, unlike ODIS–RPW statistical sampling data, does not have sampling error. *Id.* at 5. To illustrate the potential impact of switching from ODIS–RPW statistical estimates to census data, the Postal Service provides a comparison of results for the FY 2016 time period. *Id.* at 6–9.

III. Notice and Comment

The Commission establishes Docket No. RM2017–7 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's Web site at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Three no later than August 16, 2017. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is designated as officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2017–7 for consideration of the matters raised by the Petition of the United States Postal Service Requesting

[1] Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytical Principles (Proposal Three), June 22, 2017 (Petition).

Initiation of a Proceeding to Consider a Proposed Change in Analytical Principles (Proposal Three), filed June 22, 2017.

2. Comments by interested persons in this proceeding are due no later than August 16, 2017.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2017–13830 Filed 6–29–17; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0409; FRL–9955–66–Region 9]

Approval of California Air Plan Revisions, Great Basin Unified Air Pollution Control District and Town of Mammoth Lakes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Great Basin Unified Air Pollution Control District (GBUAPCD) and the Town of Mammoth Lakes portion of the California State Implementation Plan (SIP). These revisions concern particulate matter (PM) emissions from wood burning devices and road dust in the Town of Mammoth Lakes. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: Any comments on this proposal must arrive by July 31, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0409 at *http://www.regulations.gov,* or via email to Andrew Steckel, Rulemaking Office Chief at *Steckel.Andrew@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov.* For either manner of submission, 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, (415) 947–4125, *vineyard.christine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA. This proposal addresses the following local rules:

- GBUAPCD Rule 431, Particulate Matter (except paragraphs M and N).
- Town of Mammoth Lakes Municipal Code Chapter 8.30, Particulate Emissions Regulations (except paragraphs 8.30.110 and 8.30.120).

In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on a particular rule, we may adopt as final the rule that is not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: November 14, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Editorial note: This document was received for publication by the Office of the Federal Register on June 20, 2017.

[FR Doc. 2017–13197 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0011; FRL–9963–94-Region 8]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List: Partial Deletion of the Mystery Bridge Road/U.S. Highway 20 Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 8 is issuing a notice of Intent to Partially Delete the property currently owned by Tallgrass Energy Partners, LP (formerly owned by KM Upstream LLC and hereinafter referred to as the former KMI Property), on the Mystery Bridge Road/U.S. Highway 20 Site (Site) from the National Priorities List (NPL). The Site is located in Natrona County, northeast of Casper, Wyoming. EPA requests public comment on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution and Contingency Plan (NCP). The EPA and the State of Wyoming, through the Wyoming Department of Environmental Quality (WDEQ), have determined that all appropriate response actions, other than maintenance of institutional controls and five-year reviews, have been completed for the former KMI source area and the resultant groundwater contamination. However, this deletion does not preclude future actions under Superfund.

This partial deletion pertains to the former KMI Property of OU1 and OU2 formerly containing the benzene, toluene, ethylbenzene, and total xylenes (collectively known as BTEX) groundwater plume and source soils, respectively. The remaining area and media of both OU1 and OU2 containing the volatile halogenated organic chemicals (VHOs) source soils and

plume, which are attributable to the Dow Chemical Company/Dowell Schlumberger, Inc. (DOW/DSI) facility, will remain on the NPL and are not being considered for deletion as part of this action. A map and the description of the surveyed boundaries of the former KMI Property are included in the docket and at the information repositories listed below.

DATES: Comments concerning this action must be received by July 31, 2017.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1910–0011, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments.
- *Email:* Andrew Schmidt (*schmidt.andrew@epa.gov*)
- *Mail:* Andrew Schmidt, Remedial Project Manager, 8EPR–SR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202.
- *Hand Delivery:* Andrew Schmidt, Remedial Project Manager, 8EPR–SR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1910–0011. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The Web site, *http://www.regulations.gov,* is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket

All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at: U.S. EPA Region 8, Superfund Records Center & Technical Library, 1595 Wynkoop Street, Denver, CO 80202–1129.

Viewing hours: 8 a.m. to 4:00 p.m., Monday through Thursday, excluding holidays;

Contact: Andrew Schmidt; (303) 312–6283; email: *schmidt.andrew@epa.gov* and Natrona County Public Library, Reference Desk, 307 East 2nd Street, Casper, WY 82601–2593, (307) 777–7092.

Monday–Thursday: 9 a.m.–6 p.m. Friday and Saturday: 9 a.m.–5 p.m.

FOR FURTHER INFORMATION CONTACT: Andrew Schmidt, Remedial Project Manager, 8EPR–SR, U.S. Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129, (303) 312–6283, *email: schmidt.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' section of the **Federal Register**, we are publishing a direct final notice of Partial Deletion for the former KMI Property containing portions of Operable Unit 1 and 2, and the former BTEX impacted areas, of the Mystery Bridge Road/U.S. Highway 20 Superfund Site (Site) without prior notice of Intent for Partial Deletion because EPA views this as a noncontroversial revision and anticipates no adverse comment. We have explained our reasons for this partial deletion in the preamble to the direct final notice of Partial Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this partial deletion action, we will not take further action on this notice of Intent for Partial Deletion. If we receive adverse comment(s), we will withdraw the direct final notice of Partial Deletion based on this notice of Intent for Partial Deletion. We will, as appropriate, address all public comments in a subsequent final notice of Partial Deletion based on this notice of Intent for Partial Deletion. We will not institute a second comment period on this notice of Intent for Partial Deletion. Any parties interested in commenting must do so at this time.

For additional information, see the direct final notice of Partial Deletion, located in the Rules section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

The authority citation for Part 300 is continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: May 1, 2017.

Debra H. Thomas,

Acting Regional Administrator, U.S. Environmental Protection Agency, Region 8.

[FR Doc. 2017–13679 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 20

[GN Docket No 13–111; Report No. 3079]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration.

SUMMARY: A Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding by Lee G. Petro, on behalf of The Wright Petitioners.

DATES: Oppositions to the Petition must be filed on or before July 17, 2017. Replies to an opposition must be filed on or before July 25, 2017.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Melissa Conway, Mobility Division, Wireless Telecommunications Bureau,

at (202) 418–2887 or email: *Melissa.Conway@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3079, released June 22, 2017. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. It also may be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5.U.S.C. because no rules are being adopted by the Commission.

Subject: In the Matter of Promoting Technological Solutions to Combat Contraband Wireless Device Use in Correctional Facilities, FCC 17–25, published at 82 FR 22742, May 18, 2017, in GN Docket No. 13–111. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2017–13688 Filed 6–29–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 11

[PS Docket No. 15–94; FCC–17–74]

Blue Alert EAS Event Code

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes to revise its rules governing the Emergency Alert System (EAS) to incorporate a new event code, ''BLU'', for Blue Alerts. Adding this event code would allow alert originators to issue an alert whenever a law enforcement officer is injured or killed, missing in connection with their official duties, or if there is an imminent and credible threat to cause death or serious injury to law enforcement officers.

DATES: Comments are due on or before July 31, 2017 and reply comments are due on or before August 29, 2017.

ADDRESSES: You may submit comments, identified by PS Docket No. 15–94, by any of the following methods:

- *Federal Communications Commission's Web site: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gregory Cooke, Deputy Division Chief, Policy and Licensing Division, Public Safety and Homeland Security Bureau, at (202) 418–2351, or by email at *Gregory.Cooke@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (*NPRM*) in PS Docket No. 15–94, FCC 17–74, adopted on June 22, 2017, and released on June 22, 2017. The full text of this is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–1257), 445 12th Street SW., Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed 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).

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *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 9300 East Hampton Drive, Capitol Heights, MD 20743.
- 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).

Synopsis

I. Introduction

1. In this *NPRM,* we propose to revise the Federal Communications Commission's (Commission or FCC) Emergency Alert System (EAS) rules to adopt a new EAS event code that will allow the transmission of ''Blue Alerts'' to the public over the EAS. In doing so, we propose measures to advance the important public policy of protecting our nation's law enforcement officials through facilitating the apprehension of suspects who pose an imminent and credible threat to law enforcement officials and aiding search efforts to locate missing officers. Further, by initiating this proceeding, we also seek

to promote the development of compatible and integrated Blue Alert plans throughout the United States, consistent with the Rafael Ramos and Wenjian Liu National Blue Alert Act of 2015 (Blue Alert Act) and the need articulated by the Office of Community Oriented Policing Service (COPS Office) of the United States Department of Justice (DOJ) to establish a dedicated EAS event code for Blue Alerts.

II. Background

2. *The EAS.* The EAS is a national public warning system through which broadcasters, cable systems, and other service providers (EAS Participants) deliver alerts to the public to warn them of impending emergencies and dangers to life and property. Although the primary purpose of the EAS is to equip the President with the capability to provide immediate communications and information to the general public during periods of national emergency, the EAS also is used by other federal agencies, such as the National Weather Service (NWS), to deliver weather-related alerts, as well as by state and local governments to distribute other alerts such as AMBER Alerts. EAS Participants are required to deliver Presidential alerts; delivery of all other alerts, including NWS weather alerts and state and local EAS alerts, is voluntary. EAS alerts are configured using the EAS Protocol, which utilizes fixed codes to identify the various elements of an EAS alert so that each alert can deliver accurate, secure, and geographically-targeted alerts to the public. Of particular relevance to this proceeding, the EAS Protocol utilizes a three-character ''event code'' to describe the nature of the alert (*e.g.,* ''CAE'' signifies a Child Abduction Emergency, otherwise known as an AMBER Alert). EAS alerts are distributed in two ways: (1) Over-the-air, through a hierarchical, broadcast-based ''daisy chain'' distribution system, and (2) over the Internet, through the Federal Emergency Management Agency's Integrated Public Alert and Warning System (IPAWS), which simultaneously sends data-rich alerts in the Common Alerting Protocol (CAP) format to various public alerting systems.

3. *Blue Alerts.* The Blue Alert Act was enacted to encourage, enhance, and integrate the formation of voluntary ''Blue Alert plans throughout the United States in order to disseminate information when a law enforcement officer is seriously injured or killed in the line of duty, is missing in connection with the officer's official duties, or an imminent and credible threat that an individual intends to cause the serious injury or death of a law enforcement officer is received, and for other purposes.'' As required by the Blue Alert Act, DOJ has designated the COPS Office Director as the National Blue Alert Coordinator (National Blue Alert Coordinator). Accordingly, the National Blue Alert Coordinator has developed a set of voluntary guidelines (Blue Alert Guidelines) for states to use in developing their Blue Alert plans in a manner that will promote compatible and integrated Blue Alert plans throughout the United States.

4. Blue Alerts may be initiated by a law enforcement agency having primary jurisdiction over the incident. The Blue Alert Guidelines provide three criteria for Blue Alert issuance, any one of which should be met before a Blue Alert is issued. First, an alert may be issued when ''the agency confirms that a law enforcement officer has been killed, seriously injured, or attacked and with indications of death or serious injury.'' Second, an alert may be issued in the event of a ''threat to cause death or serious injury to a law enforcement officer.'' Under this criterion, the agency initiating the Blue Alert should confirm that the threat is ''imminent and credible,'' and, to the extent the threat arises from the acts of a suspect, such suspect, ''at the time of receipt of the threat,'' should be ''wanted by a law enforcement agency.'' Third, where a law enforcement officer is reported missing, an agency may issue a Blue Alert if it concludes that ''the law enforcement officer is missing in connection with the officer's official duties'' and that ''there is an indication of serious injury to or death of the law enforcement officer.'' With respect to each of these three scenarios, the agency should not issue the Blue Alert unless ''any suspect involved has not been apprehended'' and ''there is sufficient descriptive information of the suspect, including any vehicle and license tag information.'' The Blue Alert Act also provides that an alert should be issued only in those areas most likely to result in the apprehension of the suspect, and that an alert should be suspended once the suspect is apprehended.

5. Additionally, the National Blue Alert Coordinator is charged with cooperating with the Chairman of the FCC to carry out the Blue Alert Act. In its 2017 Report to Congress, the COPS Office noted that it has complied with this directive by establishing a point of contact with the FCC, and by commencing outreach efforts to pursue a dedicated EAS event code.

III. Discussion

6. We propose to revise the Commission's EAS rules to add a new ''Blue Alert'' event code to the EAS and thus ''promote compatible and integrated Blue Alert plans throughout the United States'' as called for in the Blue Alert Act. Several developments support taking this action today. The Blue Alert Act was adopted to help the states provide effective alerts to the public and law enforcement when police and other law enforcement officers are killed or in danger. In order to ensure that these state plans are compatible and integrated throughout the United States as envisioned by the Blue Alert Act, the Blue Alert Coordinator has made a series of recommendations to Congress. Among them, the Blue Alert Coordinator identified the need for a dedicated EAS event code for Blue Alerts and noted the alignment of the EAS with the implementation of the Blue Alert Act. We propose that by adopting a dedicated EAS event code to deliver Blue Alerts, our rules can help facilitate the delivery of Blue Alerts to the public in a uniform and consistent manner that promotes the compatible and integrated Blue Alert plans contemplated by the Blue Alert Act. We seek comment on this proposal below.

7. We propose to amend Section 11.31(e) of the EAS rules to add a new ''BLU'' event code to the codes contained within the EAS Protocol. Consistent with the guidance issued by the National Blue Alert Coordinator, we anticipate this code would be used by alert originators to disseminate information related to (1) the serious injury or death of a law enforcement officer in the line of duty, (2) an officer who is missing in connection with their official duties, or (3) an imminent and credible threat that an individual intends to cause serious injury to, or kill, a law enforcement officer. We also propose that such alerts would be confined to those areas most likely to facilitate capture of the suspect, and would be suspended when the suspect is apprehended. As with other non-Presidential alerts, carriage of Blue Alerts and use of the Blue Alert event code would be voluntary. We seek comment on this proposal.

8. *Efficacy of the EAS as a mechanism for delivering Blue Alerts.* We seek comment on the efficacy of the EAS as a mechanism for the delivery of Blue Alerts. We note that, for over two decades, the EAS has proven to be an effective method of alerting the public and saving lives and property. EAS Participants continue to voluntarily

transmit thousands of alerts and warnings annually regarding severe weather threats, child abductions, and other local emergencies.

9. We seek comment on whether the current system could accommodate Blue Alerts as effectively as it does these other types of alerts. Are there constraints that would impede the ability of the EAS to contain the information required under the Blue Alert Guidelines? For example, EAS alerts are subject to a two-minute time limit. Can the information required by the Blue Alert Guidelines be communicated within a two-minute time frame? We note that EAS alerts delivered over the IPAWS can contain detailed text files, non-English alerts, or other content-rich data that is not available to EAS alerts delivered via the broadcast-based daisy chain. Do Blue Alerts contain extra text files or other data-rich content that would benefit from IPAWS' capabilities? Would it have a negative impact on the value of an EAS Blue Alert that such data-rich content may not be delivered to all EAS Participants, depending on whether they receive the alert through IPAWS or through the broadcast-based daisy chain?

10. Further, EAS Alerts are limited to the geographic contours and service areas of broadcasters and cable service providers. In light of this, are EAS alerts suited to deliver Blue Alerts in a targeted geographic manner, consistent with the Blue Alert Act, which provides that Blue Alerts, to the maximum extent practicable, ''be limited to the geographic areas most likely to facilitate the apprehension of the suspect involved or which the suspect could reasonably reach, which should not be limited to state lines''? Can EAS Participants distribute Blue Alerts to such smaller, more narrowly targeted geographic areas? We note that, in the future, if ATSC 3.0 DTV is approved by the Commission as proposed in the *ATSC 3.0 NPRM,* television broadcasters using ATSC 3.0 expect to have the capability of tailoring emergency alert information for specific geographic areas. In particular, what is the ability of small cable operator EAS Participants to limit the geographic area of a Blue Alert? To what extent do states use the EAS to send Blue Alerts? Do any states send Blue Alerts outside of the EAS structure? What has been their experience? Would the EAS serve as a more effective means of conveying the information required by the Blue Alert Guidelines?

11. *Implementation of Blue Alerts.* We seek comment on whether—assuming that the EAS would be an efficient manner of distributing Blue Alerts—the establishment of a dedicated EAS event code would help to facilitate the implementation of the Blue Alert Guidelines in a compatible and integrated manner nationwide, as contemplated by the Blue Alert Act. The COPS Office states ''a dedicated Blue Alert EAS event code would serve as the central and organizing element for Blue Alert plans coast-to-coast and greatly facilitate the work of the National Blue Alert Network.'' We seek comment on this statement.

12. As of November 2016, 27 states have implemented Blue Alert plans. We observe that states' implementation of Blue Alert plans vary. For example, Montana and Florida utilize the ''Law Enforcement Emergency'' (LEW) EAS event code to transmit Blue Alerts, whereas Washington is creating its own ''Blue Alert System'' for voluntary cooperation between law enforcement, and radio, television, cable, and satellite systems. To what extent do current state guidelines for delivering a Blue Alert differ from the Blue Alert Guidelines? Would a dedicated EAS event code help ensure that both Blue Alerts and related outreach are undertaken in a consistent manner nationally? We seek comment on the distribution methods states currently employ to deliver Blue Alerts. To the extent states use different distribution methods to deliver Blue Alerts, do these various distribution methods detract from the effectiveness of Blue Alerts? We seek comment on the experience of any states that have adopted Blue Alerts as part of their statewide alerting systems. We seek comment on whether the adoption of a dedicated EAS Blue Alert event code would encourage EAS Participants to deliver Blue Alerts.

13. We additionally ask whether availability of a dedicated Blue Alert EAS event code would promote the adoption of additional Blue Alert systems throughout the nation. According to the COPS Office, a dedicated EAS event code would ''facilitate and streamline the adoption of new Blue Alert plans throughout the nation and would help to integrate existing plans into a coordinated national framework.'' As the National Blue Alert Coordinator noted in its 2016 Report to Congress, a majority of states and territories do not yet have Blue Alert systems. Would facilitating law enforcement agencies' ability to utilize existing EAS distribution networks alleviate much of the burden associated with designing and implementing Blue Alert systems and plans? Would the implementation of a dedicated Blue Alert EAS code encourage states that do not have Blue Alert plans to adopt, in whole or in part, existing procedures of states that have implemented Blue Alert plans? Has the lack of a dedicated Blue Alert EAS event code impeded adoption of Blue Alert plans? Further, would utilizing the nationwide EAS architecture help integrate existing plans into a coordinated national framework? In this regard, would integrating state Blue Alert plans into the EAS help individual states work together when suspects or threats cross state borders, as envisioned by the Blue Alert Act?

14. Alternately, we seek comment on whether existing event codes are sufficient to convey Blue Alert information. According to the COPS Office, there is a lack of urgency associated with existing event codes, which do not ''suggest immediate action on the part of broadcasters.'' As noted above, at least two states utilize the ''Law Enforcement Warning'' (LEW) EAS code to transmit Blue Alerts. The COPS Office observes, however, that the LEW event code is used for events such as road closures and notifying drivers of hazardous road conditions and is not an effective means to transmit Blue Alerts. We seek comment on this observation. Is the use of LEW effective to provide information to help protect law enforcement officials? For what purposes is LEW otherwise used? Does utilizing an existing EAS code for a Blue Alert detract from the existing code's ability to serve its intended purpose? Without adoption of a Blue Alert code, would law enforcement agencies be hampered by being forced to use codes that do not directly apply to the situation, nor convey the necessary information? Further, would the use of existing EAS event codes to broadcast a Blue Alert create confusion? Do other event codes contain instructions that might confuse the public or direct the public to take unsafe actions in response to the underlying situation? For example, in the 2016 *NWS Report and Order,* the Commission adopted new dedicated event codes for certain weather events, noting that the existing TOR event code for tornados provided the public with incorrect guidance about what actions to take in response to hurricane-related weather events, such as storm surges. Is there a similar risk of confusion with using existing EAS event codes in lieu of a dedicated Blue Alert event code?

15. *Public Awareness and Outreach.* We seek comment on how the public may respond to Blue Alert EAS codes. Would a dedicated Blue Alert EAS event code allow law enforcement to provide a warning that the public

recognizes immediately as a Blue Alert, *e.g.,* because Blue Alerts would be issued only under specific criteria that are nationally consistent? The COPS Office states that a dedicated EAS event code would ''convey the appropriate sense of urgency'' and ''galvanize the public awareness necessary to protect law enforcement officers and the public from extremely dangerous offenders.'' We seek comment on this position. Would a dedicated event code facilitate consistent and effective public outreach educating the public to recognize and respond to Blue Alerts?

16. In this regard, we seek comment on what actions states have taken to educate the public on Blue Alerts and appropriate responses to Blue Alerts. For example, we note that the Blue Alert Foundation has prepared model Public Service Announcements (PSAs) for use by states to educate the public about Blue Alerts. Have states adopted these PSAs or other types of outreach to educate the public about Blue Alerts and appropriate responses to them? How often have Blue Alerts been activated and through what means or media have they been issued? How has the public reacted to Blue Alerts? In the past, the Commission has noted its concern that over-alerting or alerting to unaffected areas can lead to alert fatigue. Has public response indicated that is the case in connection with Blue Alerts? We encourage commenters to provide examples of all available public responses to Blue Alerts that have been delivered since the adoption of the Blue Alert Act and DOJ's Blue Alert Guidelines.

17. *Timeframe.* We seek comment on the timeframe in which a dedicated Blue Alert EAS event code could be implemented. In the *NWS Report and Order,* the Commission required EAS equipment manufacturers to integrate the severe weather-related EAS event codes into equipment yet to be manufactured or sold, and to make necessary software upgrades available to EAS Participants, no later than six months from the effective date of the rules, reasoning that the prompt deployment of alerts using the new codes would be consistent with the safety of the public in affected areas. We believe that adding a Blue Alert EAS event code would trigger similar technical and public safety requirements regarding equipment readiness. We therefore propose that EAS equipment manufacturers should integrate the Blue Alert event code into equipment yet to be manufactured or sold, and make necessary software upgrades available to EAS Participants, no later than six months from the effective date of the rules. We seek comment on this proposal.

18. With regard to EAS Participants, we note that in the NWS proceeding the Commission allowed EAS Participants to implement the new event codes on a voluntary basis. The Commission further noted that it has taken this approach when it has adopted other new EAS event codes in the past, and that the record did not reflect any basis to take a different approach. We therefore propose to take a similar approach here and would allow EAS Participants to upgrade their equipment (whether through new equipment that is programmed to contain the code or through implementing a software upgrade to install the code into equipment already in place) on a voluntary basis until such time as their equipment is replaced. We seek comment on our proposal. If commenters disagree with our analysis or proposed timeline, they should specify alternatives and the specific technical bases for such alternatives.

19. *Wireless Emergency Alerts.* We note that along with the EAS, a primary public alert warning system regulated by the Commission is Wireless Emergency Alerts (WEA), a system that allows wireless providers (participating CMRS Providers) to voluntarily deliver critical warnings and information to Americans through their wireless phones. In its 2017 Report to Congress, the COPS Office notes that many Americans depend on both the EAS and WEA for public alerts and warnings. The COPS Office goes on to note its intent that Blue Alerts be delivered to the public over wireless devices as well as over the EAS. We note that EAS event codes are not required by the Commission's rules for a WEA message to be processed, but seek comment on whether the adoption of a dedicated EAS code for Blue Alerts would have any effect on WEA. For example, would the use of a Blue Alert EAS event code have any impact on how the IPAWS infrastructure and the networks of participating CMRS Providers would process a Blue Alert WEA? To what extent, if any, have states used WEA to deliver Blue Alerts to the public? Have such WEA messages been initiated by the use of existing EAS event codes?

20. Would the adoption of a dedicated EAS event code help ensure that Blue Alerts issued over WEA are swiftly processed and delivered to the public? If we were to adopt a dedicated Blue Alert EAS event code, and the alert originator were to select ''BLU'' as the event code type, could this automatically prepopulate the WEA message—thereby saving critical seconds—with uniform language that might be applicable to all Blue Alerts (such as by automatically including alert message text saying ''This is a Blue Alert for [area]'')? We assume that WEA Blue Alerts would be classified as either an Imminent Threat Alert or the newly adopted Public Safety Message, depending on the circumstances. We seek comment on this assumption, and ask whether alert initiators, Participating CMRS providers, or other WEA stakeholders believe it would be helpful to receive additional guidance or direction regarding how Blue Alerts should be classified for purposes of WEA. Are there other reasons adopting a dedicated EAS Blue Alert event code would facilitate or otherwise affect the delivery of Blue Alerts to the public over WEA?

21. *Costs and Benefits.* We seek comment on the total costs and benefits associated with the proposed addition of Blue Alerts to the EAS. For those states that have adopted State Blue Alert Plans, have Blue Alerts been effective in protecting law enforcement officers and/or apprehending criminals? Would a dedicated EAS code produce a more efficient result than utilizing an existing event code or alternate delivery mechanism?

22. In the background section of this *NPRM,* we describe how AMBER Alerts are a voluntary partnership between law-enforcement agencies, broadcasters, transportation agencies, and the wireless industry to activate an urgent bulletin in the most serious child-abduction cases. Would the adoption of a dedicated EAS event code help facilitate a similar partnership to promote the safety of law enforcement officers? Would Blue Alerts have a similar impact as AMBER Alerts? We seek comment on whether statistical information concerning AMBER Alerts is relevant to Blue Alerts. The DOJ reports that AMBER Alerts were directly responsible for recovering more than 25% of children reported missing in 2015. According to DOJ statistics, 868 children have been rescued due to Amber Alerts. In 2015 alone, 50 of the 153 recoveries were the direct result of Amber Alerts, constituting more than 25% of the recovered children reported missing that year. Is it reasonable to expect a similar success rate for EAS Blue Alerts? What is the expected reduction in time to find a lost or abducted child as a result of the introduction of the EAS Code for AMBER Alerts? Would a similar reduction of time occur with an EAS Blue Alert code?

23. We seek comment on whether introducing a dedicated EAS event code

would help save the lives of law enforcement officers or the public. We observe that 135 law enforcement officials were killed in 2016. The COPS Office argues that the EAS framework is a valuable resource that can ''expedite information sharing and facilitate the quick apprehension of dangerous criminals who pose an immediate threat to law enforcement and communities they serve.'' Would utilizing a dedicated event code facilitate faster information sharing and dissemination of information to the public? The COPS Office additionally argues that Blue Alerts can ''provide instructions to keep innocent persons safe and information on what to do if a suspect is spotted.'' Would a faster and more uniform means of disseminating Blue Alerts, such as through a dedicated EAS event code, save lives (whether directly as to law enforcement officials, or indirectly as to innocent bystanders that might be harmed by the same emergency)? To quantify the life-saving value of the EAS, we assign a dollar value to reductions in the risk of losing human lives, referred to as the ''Value of a Statistical Life'' (VSL). VSL describes ''the additional cost that individuals would be willing to bear for improvements in safety (that is, reductions in risks) that, in the aggregate, reduce the expected number of fatalities by one.'' We estimate that the dollar value of VSL in 2017 is approximately $9.6 million.

24. We seek comment on the benefits of a dedicated EAS Blue Alert code with respect to potentially providing an additional path of communication to others who may be best positioned to provide assistance, including off-duty public safety officials and the media. EAS Blue Alerts also could quickly provide the media with information that they can disseminate to the public. In this regard, could EAS Blue Alerts lower the amount of time that police forces devote to alerting the media, allowing more time for personnel to devote to responding to the emergency? We seek comment on this category of benefits and cost reductions.

25. We also seek comment on the costs of the proposed event code. In the *NWS Report and Order,* the Commission noted that the record indicated that the new severe weather-related codes could be implemented by EAS Participants via minimally burdensome and low-cost software downloads. Is the same true for the proposed Blue Alert event code? In the record of the *NWS Report and Order,* Monroe Electronics indicated that the new severe weather-related event codes could be implemented in its device models through a software update downloaded from its Web site, while Sage Alerting Systems indicated that end users could implement the proposed event codes in 10 minutes or less at no cost other than labor. In the *NWS Report and Order,* the Commission expected total costs for the codes adopted in that order would not exceed the one-time $3.5 million implementation cost ceiling. We believe that adopting a Blue Alert EAS event code presents similar technical issues to those raised in the NWS Order. Accordingly, we believe that the same costs would apply to the adoption of a Blue Alert EAS event code as applied to the severe weather event codes adopted in the NWS proceeding, and tentatively conclude that the costs for adding a dedicated Blue Alert EAS event code would not exceed the one-time $3.5 million implementation cost ceiling that the Commission expected in the *NWS Report and Order.* We seek comment on this analysis.

26. We believe $3.5 million represents a conservative estimate because it assumes all 28,508 broadcasters and cable companies will spend the maximum of one hour downloading and installing a Blue Alert specific software update. We note that, as of July 30, 2016, EAS Participants were required to have equipment in place that would be capable, at the minimum, of being upgraded by software to accommodate EAS modifications like what we propose here. We also believe that the actual cost imposed will fall far below the $3.5 million cost ceiling, because it is premised on the assumption that downloading the software updates will take one hour, whereas Sage estimated in the *NWS Report and Order* that a similar download and installation would take ten minutes. Further, we see no reason why the Blue Alert event code could not be bundled with a general software upgrade that EAS Participants would otherwise install anyway, during the regular course of business. We tentatively conclude that the installation costs imposed on EAS Participants, together with the software update costs incurred by equipment manufacturers, would be far below the $3.5 million ceiling estimated in the *NWS Report and Order.* We seek comment on our tentative conclusions. We also seek comment on the cost to EAS equipment manufacturers of creating software updates, testing these updates, supplying them to their customers, and providing any related customer support. We recognize that potential costs also may include management oversight software updates.

27. The COPS Office observes that a dedicated event code would convey the necessary sense of urgency and galvanize the public awareness necessary to protect law enforcement and the public from dangerous offenders, avoid utilizing existing codes which are used for mundane informational purposes, facilitate the adoption of new Blue Alert plans and integrate existing plans into a cohesive framework, and serve as a central and organizing element for Blue Alert plans nationally. We acknowledge DOJ's guidance and expertise as to the potential benefits of Blue Alerts, and combine that with our own analysis to support the tentative conclusion that the benefits of the proposed event code will outweigh its costs. We seek comment on this tentative conclusion.

28. Finally, are there costs or benefits that should be considered that are not captured in the above discussion? Are there alternative or additional approaches that could increase benefits and/or reduce costs? We seek comment on whether there are alternative or additional measures that the Commission could take to improve the introduction of Blue Alerts over the EAS, in order to promote the important public policy objective of protecting our nation's law enforcement officials.

IV. Initial Regulatory Flexibility Analysis

29. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *NPRM.* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments in the *NPRM.* The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

30. In this *NPRM,* the Commission proposes adding a new Emergency Alert System (EAS) Event Code, covering Blue Alerts (''Blue Alert Warning''). The Blue Alert Act charges the Community Oriented Policing Service (COPS Office) with identifying policies and procedures for disseminating Blue Alerts to the public that are effective, and can be implemented with no additional cost. Blue Alert carriage and

use of the Blue Alert event code would be voluntary. In its 2016 Report to Congress, the COPS Office identified a dedicated EAS event code for Blue Alerts as a means of disseminating Blue Alerts to the public, and a necessary element to align the EAS with implementation of the Blue Alert Act overall. EAS Participants who decide to carry the Blue Alert would be able to accommodate the new code with a software upgrade of equipment already in place but not yet capable of handling these codes (any new equipment allowed under existing rules is either similarly upgradeable or will already be programmed to handle the code). In this *NPRM,* we seek comment on whether adding a ''Blue Alert'' code to the EAS would serve the public interest by furthering the goal of the Blue Alert Act by disseminating information to the public that protects law enforcement officials and the public at large.

B. Legal Basis

31. Authority for the actions proposed in this *NPRM* may be found in sections 1, 2, 4(i), 4(o), 301, 303(r), 303(v), 307, 309, 335, 403, 624(g), 706, and 715 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(o), 301, 303(r), 303(v), 307, 309, 335, 403, 544(g), 606, and 615.

C. Description and Estimate of the Number of Small Entities to Which Rules Will Apply

32. The RFA directs agencies to provide a description of and, where feasible, an estimate of, the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). Below, we describe and estimate the number of small entity licensees that may be affected by the adopted rules.

33. *Small Businesses, Small Organizations, and Small Governmental Jurisdictions.* Our action may, over time, affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three comprehensive, statutory small entity size standards that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general, a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 28.8 million businesses. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 2007, there were approximately 1,621,215 small organizations. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data published in 2012 indicate that there were 89,476 local governmental jurisdictions in the United States. We estimate that, of this total, as many as 88,761 entities may qualify as ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

34. *Radio Stations.* This Economic Census category comprises establishments primarily engaged in broadcasting aural programs by radio to the public. Programming may originate in the station's own studio, from an affiliated network, or from external sources. The SBA has established a small business size standard for this category as firms having $38.5 million or less in annual receipts. U.S. Census Bureau data for 2012 shows that 2,849 radio station firms operated during that year. Of that number, 2,806 operated with annual receipts of less than $25 million per year, 17 with annual receipts between $25 million and $49,999,999 million and 26 with annual receipts of $50 million or more. Therefore, based on the SBA's size standard, the majority of such entities are small entities.

35. According to Commission staff review of the BIA Publications, Inc. Master Access Radio Analyzer Database as of June 2, 2016, about 11,386 (or about 99.9 percent) of 11,395 commercial radio stations had revenues of $38.5 million or less and thus qualify as small entities under the SBA definition. The Commission has estimated the number of licensed commercial radio stations to be 11,415. We note that the Commission also has estimated the number of licensed NCE radio stations to be 4,101. Nevertheless, the Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

36. We also note that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included. The Commission's estimate therefore likely overstates the number of small entities that might be affected by its action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, to be determined a ''small business,'' an entity may not be dominant in its field of operation. We further note, that it is difficult at times to assess these criteria in the context of media entities, and the estimate of small businesses to which these rules may apply does not exclude any radio station from the definition of a small business on these basis; thus, our estimate of small businesses may be over-inclusive.

37. *FM Translator Stations and Low-Power FM Stations.* FM translators and Low Power FM Stations are classified in the category of Radio Stations and are assigned the same NAICs Code as licensees of radio stations. This U.S. industry, Radio Stations, comprises establishments primarily engaged in broadcasting aural programs by radio to the public. Programming may originate in their own studios, from an affiliated network, or from external sources. The SBA has established a small business size standard which consists of all radio stations whose annual receipts are $38.5 million dollars or less. U.S. Census data for 2012 indicate that 2,849 radio station firms operated during that year. Of that number, 2,806 operated with annual receipts of less than $25 million per year, 17 with annual receipts between $25 million and $49,999,999 million and 26 with annual receipts of $50 million or more. Based on U.S. Census Bureau data, we conclude that the majority of FM Translator Stations and Low Power FM Stations are small.

38. *Television Broadcasting.* This Economic Census category ''comprises establishments primarily engaged in broadcasting images together with sound.'' These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which, in turn, broadcast the programs to the public on a predetermined schedule. Programming may originate in

their own studios, from an affiliated network, or from external sources. The SBA has created the following small business size standard for such businesses: those having $38.5 million or less in annual receipts. The 2012 Economic Census reports that 751 firms in this category operated in that year. Of that number, 656 had annual receipts of $25,000,000 or less, 25 had annual receipts between $25,000,000 and $49,999,999, and 70 had annual receipts of $50,000,000 or more. Based on this data, we therefore estimate that the majority of commercial television broadcasters are small entities under the applicable SBA size standard.

39. The Commission has estimated the number of licensed commercial television stations to be 1,384. Of this total, 1,264 stations (or about 91 percent) had revenues of $38.5 million or less, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) on February 24, 2017, and, therefore, these licensees qualify as small entities under the SBA definition. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 394. Notwithstanding, the Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

40. We note, however, that in assessing whether a business concern qualifies as ''small'' under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, another element of the definition of ''small business'' requires that an entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television broadcast station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and therefore is possibly over-inclusive.

41. *Cable and Other Subscription Programming.* This industry comprises establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (*e.g.,* limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA size standard for this industry establishes as small any company in this category which receives annual receipts of $38.5 million or less. Based on U.S. Census data for 2012, in that year 725 establishments operated for the entire year. Of that number, 488 operated with annual receipts of $10 million a year or less and 237 establishments operated with annual receipts of $10 million or more. Based on this data, the Commission estimates that the majority of establishments operating in this industry are small.

42. *Cable System Operators (Rate Regulation Standard).* The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are currently 4,600 active cable systems in the United States. Of this total, all but nine cable operators nationwide are small under the 400,000-subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

43. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000 are approximately 52,403,705 cable video subscribers in the United States today. Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

44. *Custom Computer Programming Services.* This industry is comprised of establishments primarily engaged in writing, modifying, testing, and supporting software to meet the needs of a particular customer. The SBA has developed a small business size standard for this category, which is annual gross receipts of $27.5 million or less. According to data from the 2012 U.S. Census, there were 47,918 establishments engaged in this business in 2012. Of these, 45,786 had annual gross receipts of less than $10,000,000. Another 2,132 establishments had gross receipts of $10,000,000 or more. Based on this data, the Commission concludes that the majority of the businesses engaged in this industry are small.

45. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment. The Small Business Administration has established a size standard for this industry of 1,250 or fewer employees. U.S. Census data for 2012 shows that 841 establishments operated in this industry in that year. Of that number, 828 establishments operated with fewer than 1,000 employees, 7 establishments operated with between 1,000 and 2,499 employees and 6 establishments operated with 2,500 or more employees. Based on this data, we conclude that a majority of manufacturers in this industry are small.

46. *Satellite Telecommunications.* This category comprises firms ''primarily engaged in providing telecommunications services to other establishments in the

telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' The category has a small business size standard of $32.5 million or less in average annual receipts, under SBA rules. For this category, U.S. Census Bureau data for 2012 shows that there were a total of 333 firms that operated for the entire year. Of this total, 299 firms had annual receipts of less than $25 million. Consequently, we estimate that the majority of satellite telecommunications providers are small entities.

47. *Software Publishers.* This industry comprises establishments primarily engaged in computer software publishing or publishing and reproduction. Establishments in this industry carry out operations necessary for producing and distributing computer software, such as designing, providing documentation, assisting in installation, and providing support services to software purchasers. These establishments may design, develop, and publish, or publish only. The SBA has established a size standard for this industry of annual receipts of $38.5 million per year. U.S. Census data for 2012 indicates that 5,079 firms operated in that year. Of that number, 4,697 firms had annual receipts of $25 million or less. Based on that data, we conclude that a majority of firms in this industry are small.

48. *All Other Telecommunications Providers.* The ''All Other Telecommunications'' category is comprised of establishments that are primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for ''All Other Telecommunications,'' which consists of all such firms with gross annual receipts of $32.5 million or less. For this category, U.S. Census data for 2012 shows that there were 1,442 firms that operated for the entire year. Of these firms, a total of 1,400 had gross annual receipts of less than $25 million. Thus, a majority of ''All Other Telecommunications'' firms potentially affected by the rules adopted can be considered small.

49. *Broadband Radio Service and Educational Broadband Service.* Broadband Radio Service systems, previously referred to as Multipoint Distribution Service (MDS) and Multichannel Multipoint Distribution Service (MMDS) systems, and ''wireless cable,'' transmit video programming to subscribers and provide two-way high speed data operations using the microwave frequencies of the Broadband Radio Service (BRS) and Educational Broadband Service (EBS) (previously referred to as the Instructional Television Fixed Service (ITFS)).

50. *BRS.* In connection with the 1996 BRS auction, the Commission established a small business size standard as an entity that had annual average gross revenues of no more than $40 million in the previous three calendar years. The BRS auctions resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs). Of the 67 auction winners, 61 met the definition of a small business. BRS also includes licensees of stations authorized prior to the auction. At this time, we estimate that of the 61 small business BRS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent BRS licensees that are considered small entities. After adding the number of small business auction licensees to the number of incumbent licensees not already counted, we find that there are currently approximately 440 BRS licensees that are defined as small businesses under either the SBA or the Commission's rules.

51. In 2009, the Commission conducted Auction 86, the sale of 78 licenses in the BRS areas. The Commission offered three levels of bidding credits: (i) A bidder with attributed average annual gross revenues that exceed $15 million and do not exceed $40 million for the preceding three years (small business) received a 15 percent discount on its winning bid; (ii) a bidder with attributed average annual gross revenues that exceed $3 million and do not exceed $15 million for the preceding three years (very small business) received a 25 percent discount on its winning bid; and (iii) a bidder with attributed average annual gross revenues that do not exceed $3 million for the preceding three years (entrepreneur) received a 35 percent discount on its winning bid. Auction 86 concluded in 2009 with the sale of 61 licenses. Of the ten winning bidders, two bidders that claimed small business status won 4 licenses; one bidder that claimed very small business status won three licenses; and two bidders that claimed entrepreneur status won six licenses.

52. *EBS.* The SBA's Cable Television Distribution Services small business size standard is applicable to EBS. There are presently 2,436 EBS licensees. All but 100 of these licenses are held by educational institutions. Educational institutions are included in this analysis as small entities. Thus, we estimate that at least 2,336 licensees are small businesses. Since 2007, Cable Television Distribution Services have been defined within the broad economic census category of Wired Telecommunications Carriers. Wired Telecommunications Carriers are comprised of establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; and wired broadband Internet services.'' The SBA's small business size standard for this category is all such firms having 1,500 or fewer employees. U.S. Census data for 2012 shows that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small. In addition to Census data, the Commission's internal records indicate that as of September 2014, there are 2,207 active EBS licenses. The Commission estimates that of these 2,207 licenses, the majority are held by non-profit educational institutions and school districts, which are by statute defined as small businesses.

53. *Direct Broadcast Satellite (''DBS'') Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the subscriber's location. DBS is now included in SBA's economic census category ''Wired Telecommunications Carriers.'' The Wired Telecommunications Carriers

industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution; and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. The SBA determines that a wireline business is small if it has fewer than 1500 employees. U.S. Census data for 2012 indicates that 3,117 wireline companies were operational during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Based on that data, we conclude that the majority of wireline firms are small under the applicable standard. However, currently only two entities provide DBS service, which requires a great deal of capital for operation: DIRECTV (owned by AT&T) and DISH Network. DIRECTV and DISH Network each report annual revenues that are in excess of the threshold for a small business. Accordingly, we must conclude that internally developed FCC data are persuasive that, in general, DBS service is provided only by large firms.

54. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. U.S. Census data for 2012 shows that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

55. *Wireless Communications Service.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission established small business size standards for the wireless communications services (WCS) auction. A ''small business'' is an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' is an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these small business size standards. The Commission auctioned geographic area licenses in the WCS service. In the auction, there were seven winning bidders that qualified as ''very small business'' entities, and one that qualified as a ''small business'' entity.

56. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1000 employees or more. Thus, under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

57. None.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

58. The RFA requires an agency to describe any significant, specifically small business alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) and exemption from coverage of the rule, or any part thereof, for small entities.''

59. The rule changes contemplated by the *NPRM* would implement certain EAS warning codes that are unique, and implemented by small entity and larger-sized regulated entities on a voluntary basis through equipment already in place (or a software upgrade thereof). The costs to EAS Participants associated with implementing the codes contained in the proposed rule changes are expected to be *de minimis* and limited to the cost of labor for downloading software updates, to the extent any updates are required at all. Nevertheless, we have invited comment on the costs associated with implementation of the proposed Blue Alert code in order to more fully understand the impact of the proposed action and assess whether any action is needed to assist small entities. Similarly, while we believe that the costs incurred by equipment manufacturers to write a few lines of code to implement the Blue Alert code will be minimal, we have also invited comments on the cost to EAS equipment manufacturers of creating software updates, testing these updates, supplying them to their customers, and providing any related customer support. Additionally, we have invited Commenters to propose steps that the Commission may take to further minimize any significant economic impact on small entities. When considering proposals made by other parties, commenters are invited to propose significant alternatives that serve the goals of these proposals.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

60. None.

V. Procedural Matters

A. Ex Parte Rules

61. The proceeding this *NPRM* initiates 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.

B. Regulatory Flexibility Analysis

62. As required by the Regulatory Flexibility Act of 1980, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules addressed in this document. The IRFA is set forth in Appendix B. Written public comments are requested in the IRFA. These comments must be filed in accordance with the same filing deadlines as comments filed in response to this *NPRM,* as set forth on the first page of this document, and have a separate and distinct heading designating them as responses to the IRFA.

C. Paperwork Reduction Analysis

63. 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.

II. Ordering Clauses

64. Accordingly, *It is ordered* that pursuant to sections 1, 2, 4(i), 4(o), 301, 303(r), 303(v), 307, 309, 335, 403, 624(g), 706, and 715 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(o), 301, 303(r), 303(v), 307, 309, 335, 403, 544(g), 606, and 615, this *Notice of Proposed Rulemaking is Adopted.*

65. *It is Further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *Shall send* a copy of this *Notice of Proposed Rulemaking* including the Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 11

Emergency Alert System.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 11 as follows:

PART 11—EMERGENCY ALERT SYSTEM (EAS)

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 47 U.S.C. 151, 154 (i) and (o), 303(r), 544(g) and 606.

■ 2. Amend § 11.31 by adding entry of ''Blue Alert'' to the table in paragraphs (e) to read as follows:

§ 11.31 EAS protocol.

* * * * *

(e) * * *

Nature of activation	Event codes
* * * * *	
State and Local Codes (Optional):	
* * * * *	
Blue Alert	BLU.
* * * * *	

* * * * *

[FR Doc. 2017–13718 Filed 6–29–17; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 82, No. 125
Friday, June 30, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 27, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding (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 July 31, 2017 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), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *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.

Farm Service Agency

Title: Disaster Assistance—General (7 CFR part 1945–A).

OMB Control Number: 0560–0170.

Summary of Collection: The regulation at 7 CFR 759, defines the responsibilities of the Secretary of Agriculture in making disaster area determinations, the types of incidents that can result in a disaster area determination, and the factors used in making disaster area determinations. The determination of a disaster area is prerequisite to authorizing emergency (EM) loans to qualified farmers as outlined in 7 CFR 764. EM loan funds may be used to restore or replace essential property, pay all or part of production costs incurred by the farmer or rancher in the year of the disaster, pay for essential family living expenses, pay to reorganize the farming operation or refinance USDA and non-USDA creditors. The information collection occurs when the Secretary receives a letter from an individual farmer, local government officials, State Governor, State Agriculture Commissioners, State Secretaries of Agriculture, other State government officials, and Indian Tribal Council, requesting a Secretarial natural disaster determination. Supporting documentation of losses for all counties having disaster is provided by the County Emergency Boards in the form of a report entitled ''Loss Assessment Report'' (LAR).

Need and Use of the Information: The Farm Service Agency (FSA) will collect the following information to determine if the county is eligible to qualify for a natural disaster designation: (1) The nature and extent of production losses; (2) the number of farmers who have sustained qualifying production losses; and (3) the number of farmers that have sustained qualifying production losses that other lenders in the county have indicated that they will not be in a position to finance. The collection of information is necessary to determine whether the counties did sustain sufficient production losses to qualify for a natural disaster designation. The information will be used by FSA to process request for Secretarial natural disaster designations.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 401.

Frequency of Responses: Reporting: On occasion; Annually.

Total Burden Hours: 214.

Farm Service Agency

Title: Customer Data Worksheet Request for Business Partner Record Change.

OMB Control Number: 0560–0265.

Summary of Collection: Core Customer Data is required in order to identify USDA program participants and ensure that benefits are directed to the correct customer and respective Tax Identification Numbers. USDA requires this data to ensure that customers can be validated and also to provide a necessary basis for pursuing legal remedies in the event of error or fraud. There is no public law regarding the use or collection of Core Customer Data. The option to document and track Core Customer Data changes is necessary to ensure the integrity of the data and to provide the Farm Service Agency (FSA), Natural Resources and Conservation Service and Rural Development a method of verifying the validity of the information, and provide a necessary basis for pursuing legal remedies when needed.

Need and Use of the Information: Core Customer Data is necessary to input customer information for identity purposes and to provide a point of contact for the respective customer and a valid Tax Identification Number to direct program benefits to. The AD–2047 will be used to document Corel Customer Data changes and also to provide a method to identify who made applicable changes and when this was done. Failure to collect and timely maintain the data collected will result in erroneous/out dated point of contact information, which could result in program information and benefits being directed to incorrect recipients.

Description of Respondents: Individuals or households; Business or other for-profit; Farms.

Number of Respondents: 56,926.

Frequency of Responses: Reporting: Other (when necessary).

Total Burden Hours: 9,678.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–13747 Filed 6–29–17; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Determination of Total Amounts of Fiscal Year 2018 WTO Tariff-Rate Quotas for Raw Cane Sugar and Certain Sugars, Syrups and Molasses

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: The Office of the Secretary of the Department of Agriculture (the Secretary) announces the establishment of the Fiscal Year (FY) 2018 (October 1, 2017–September 30, 2018) in-quota aggregate quantity of raw cane sugar at 1,117,195 metric tons raw value (MTRV), and the establishment of the FY 2018 in-quota aggregate quantity of certain sugars, syrups, and molasses (also referred to as refined sugar) at 182,000 MTRV.

DATES: *Effective Date:* June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Import Policies and Export Reporting Division, Foreign Agricultural Service, Department of Agriculture, 1400 Independence Avenue SW., AgStop 1021, Washington, DC 20250–1021; by telephone (202) 720–2916; by fax (202) 720–0876; or by email *souleymane.diaby@fas.usda.gov*.

SUPPLEMENTARY INFORMATION: The provisions of paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the U.S. Harmonized Tariff Schedule (HTS) authorize the Secretary to establish the in-quota tariff-rate quota (TRQ) amounts (expressed in terms of raw value) for imports of raw cane sugar and certain sugars, syrups, and molasses that may be entered under the subheadings of the HTS subject to the lower tier of duties during each fiscal year. The Office of the U.S. Trade Representative (USTR) is responsible for the allocation of these quantities among supplying countries and areas.

Section 359(k) of the Agricultural Adjustment Act of 1938, as amended, requires that at the beginning of the quota year the Secretary of Agriculture establish the TRQs for raw cane sugar and refined sugars at the minimum levels necessary to comply with obligations under international trade agreements, with the exception of specialty sugar.

Notice is hereby given that I have determined, in accordance with paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the HTS and section 359(k) of the 1938 Act, that an aggregate quantity of up to 1,117,195 MTRV of raw cane sugar may be entered or withdrawn from warehouse for consumption during FY 2018. This is the minimum amount to which the United States is committed under the WTO Uruguay Round Agreements. I have further determined that an aggregate quantity of 182,000 MTRV of sugars, syrups, and molasses may be entered or withdrawn from warehouse for consumption during FY 2018. This quantity includes the minimum amount to which the United States is committed under the WTO Uruguay Round Agreements, 22,000 MTRV, of which 20,344 MTRV is established for any sugars, syrups and molasses, and 1,656 MTRV is reserved for specialty sugar. An additional amount of 160,000 MTRV is added to the specialty sugar TRQ for a total of 161,656 MTRV.

Because the specialty sugar TRQ is first-come, first-served, tranches are needed to allow for orderly marketing throughout the year. The FY 2018 specialty sugar TRQ will be opened in five tranches. The first tranche, totaling 1,656 MTRV, will open October 2, 2017. All specialty sugars are eligible for entry under this tranche. The second tranche will open on October 18, 2017, and be equal to 48,000 MTRV. The third tranche of 48,000 MTRV will open on January 23, 2018. The fourth and fifth tranches of 32,000 MTRV each will open on April 17, 2018, and July 17, 2018, respectively. The second, third, fourth, and fifth tranches will be reserved for organic sugar and other specialty sugars not currently produced commercially in the United States or reasonably available from domestic sources.

* Conversion factor: 1 metric ton = 1.10231125 short tons.

Dated: June 21, 2017.

Jason Hafemeister,

Acting Deputy Under Secretary, Trade and Foreign Agricultural Affairs.

Dated: June 22, 2017.

Robert Johansson,

Acting Under Secretary, Farm Production and Conservation.

[FR Doc. 2017–13781 Filed 6–29–17; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0053]

Notice of Availability of an Evaluation of the Highly Pathogenic Avian Influenza and Newcastle Disease Status of Japan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we are proposing to recognize Japan as being free of highly pathogenic avian influenza and Newcastle disease. This proposed recognition is based on a risk evaluation we have prepared in connection with this action, which we are making available for review and comment.

DATES: We will consider all comments that we receive on or before July 31, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0053*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0053, 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-2016-0053* 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: Dr. Kelly Rhodes, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, USDA, 4700 River Road, Unit 38, Riverdale, MD 20737–1231; *Kelly.Rhodes@aphis.usda.gov*; (301) 851–3315.

SUPPLEMENTARY INFORMATION:

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, including highly pathogenic avian

influenza (HPAI) and Newcastle disease. Within part 94, § 94.6 contains requirements governing the importation of carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions where HPAI and Newcastle disease is considered to exist.

In accordance with § 94.6(a)(1)(i) the Animal and Plant Health Inspection Service (APHIS) maintains a list of regions in which Newcastle disease is not considered to exist. Paragraph (a)(1)(ii) states that APHIS will add a region to this list after it conducts an evaluation of the region and finds that Newcastle disease is not likely to be present in its commercial bird or poultry populations.

In accordance with § 94.6(a)(2)(i), APHIS maintains a list of regions in which HPAI is considered to exist. Paragraph (a)(2)(ii) states that APHIS will remove a region from this list only after it conducts an evaluation of the region and finds that HPAI is not likely to be present in its commercial bird or poultry populations.

The regulations in 9 CFR part 92, § 92.2 contain requirements for requesting the recognition of the animal health status of a region (as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region). If, after review and evaluation of the information submitted in support of the request, APHIS believes the request can be safely granted, APHIS will make its evaluation available for public comment through a document published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

The Government of Japan has requested that APHIS evaluate the HPAI and Newcastle disease status of the country. In response to Japan's request, we have prepared an evaluation, titled ''APHIS Evaluation of the Highly Pathogenic Avian Influenza and Newcastle Disease Status of Japan'' (May 2017). Based on this evaluation, we have determined that Japan is free of both HPAI and Newcastle disease. APHIS has also determined that the surveillance, prevention, and control measures implemented by Japan are sufficient to minimize the likelihood of introducing HPAI and Newcastle disease into the United States via imports of species or products susceptible to these diseases. Our determination supports adding Japan to the Web-based list of regions in which Newcastle disease is not considered to exist and removing Japan from the Web-based list of regions in which HPAI is considered to exist.

Therefore, in accordance with § 92.2(e), we are announcing the availability of our risk evaluation of the HPAI and Newcastle disease status of Japan for public review and comment. We are also announcing the availability of an environmental assessment (EA) which has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). The evaluation and EA may be viewed on the *Regulations.gov* Web site or in our reading room. (Instructions for accessing *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this notice.) The documents are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Information submitted in support of Japan's request is available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After reviewing any comments we receive, we will announce our decision regarding the disease status of Japan with respect to HPAI and Newcastle disease in a subsequent notice.

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 26th day of June 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–13783 Filed 6–29–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0048]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Animals and Poultry, Animal and Poultry Products, Certain Animal Embryos, Semen, and Zoological Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the importation of animals and poultry, animal and poultry products, certain animal embryos, semen, and zoological animals.

DATES: We will consider all comments that we receive on or before August 29, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0048.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0048, 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-2017-0048* 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 importation of animals and poultry, animal and poultry products, certain animal embryos, and zoological animals, contact Dr. Bettina Helm, Senior Staff Veterinarian, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; (301) 851–3300. For copies of more detailed information on the information collection, contact

Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Animals and Poultry, Animal and Poultry Products, Certain Animal Embryos, Semen, and Zoological Animals.

OMB Control Number: 0579–0040.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is authorized, among other things, to prohibit or restrict the importation of animals, animal products, and other articles into the United States to prevent the introduction of animal diseases and pests. Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing APHIS' ability to compete in the world market of animal and animal product trade.

Among other things, APHIS' Veterinary Services is responsible for preventing the introduction of foreign or certain other communicable animal diseases into the United States and for rapidly identifying, containing, eradicating, or otherwise mitigating such diseases when feasible. In connection with this mission, APHIS collects information from individuals, businesses, and farms that are involved with importation of animals or poultry, animal or poultry products, or animal germplasm (semen, ooycysts, and embryos, including eggs for hatching) into the United States, as well as from foreign countries and States to support these imports. Some of the information collection activities include agreements, permits, application and space reservation requests, inspections, registers, declarations of importation, requests for hearings, daily logs, additional requirements, application for permits, export health certificates, letters, written notices, daily record of horse activities, written requests, opportunities to present views, reporting, applications for approval of facilities, certifications, arrival notices, on-hold shipment notifications, reports, affidavits, animal identification, written plans, checklists, specimen submissions, emergency action notifications, refusal of entry and order to dispose of fish, premises information, recordkeeping, and application of seals.

In addition, APHIS opens U.S. markets to animal commodities by receiving and evaluating information collection activities, such as requests for recognition of the animal health status of a region, applications for recognition of the animal health status of a region, applications for recognition of a region as historically free of a disease, requests for additional information about the region, appeal classification of animal health status, and written recommendation implementation from foreign animal health authorities seeking to engage in the regionalization process.

The information collection requirements above are currently approved by the Office of Management and Budget (OMB) under OMB control numbers 0579–0040 (Importation of Animals and Poultry, Animal and Poultry Products, Certain Animal Embryos, Semen, and Zoological Animals), 0579–0165 (Importation of Horses, Ruminants, Swine, and Dogs; Inspection and Treatment for Screwworm), 0579–0224 (Tuberculosis Testing of Imported Cattle from Mexico), 0579–0301 (Spring Viremia of Carp; Import Restrictions on Certain Live Fish, Fertilized Eggs, and Gametes), and 0579–0425 (Cattle Fever Tick; Importation Requirements for Ruminants from Mexico). After OMB approves this combined information collection package (0579–0040), APHIS will retire OMB control numbers 0579–0165, 0579–0224, 0579–0301, and 0579–0425.

We are asking OMB to approve our use of these information collection activities, as described, for an additional 3 years.

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

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

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

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

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

Estimate of burden: The public burden for this collection of information is estimated to average 0.57 hours per response.

Respondents: Foreign animal health authorities; U.S. importers; foreign exporters; veterinarians and animal health technicians in other countries; State animal health authorities; shippers, owners and operators of foreign processing plants and farms; USDA-approved zoos, laboratories, and feedlots; private quarantine facilities; and other entities involved (directly or indirectly) in the importation of animals and poultry, animal and poultry products, zoological animals, and animal germplasm.

Estimated annual number of respondents: 8,412.

Estimated annual number of responses per respondent: 65.

Estimated annual number of responses: 545,020.

Estimated total annual burden on respondents: 313,843 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 27th day of June 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–13782 Filed 6–29–17; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska 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 a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Alaska Time) Thursday, July 6, 2017. The purpose of the meeting is for the Committee to receive orientation from Commission staff and discussion regarding the status of the Committee project on voting rights.

DATES: The meeting will be held on Thursday, July 6, 2017, at 2:00 p.m. AKDT.

Public Call Information: Dial: 888–724–9513.

Conference ID: 7347511.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–724–9513, conference ID number: 7347511. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and 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 1–800–977–8339 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 Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=234.*

Please click on the ''Meeting Details'' and ''Documents'' links. 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 Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Update on Proposal—*Ana Fortes, DFO*
III. Update on Date and Location of In-Person Hearing
IV. Discussion on Potential Speakers for In-Person Hearing
V. Public Comment
VI. Next Steps
VII. Adjournment

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–13674 Filed 6–29–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

[Docket Number: 160229154–6154–02]

RIN 0660–XC023

Notice of Availability of a Final Programmatic Environmental Impact Statement for the Non-Contiguous Region of the Nationwide Public Safety Broadband Network

AGENCY: First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of availability of a final programmatic environmental impact statement.

SUMMARY: The First Responder Network Authority (''FirstNet'') announces the availability of the Final Programmatic Environmental Impact Statement for the Non-Contiguous Region (''Final PEIS''). The Final PEIS evaluates the potential environmental impacts of the proposed nationwide public safety broadband network in the Non-Contiguous Region (Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands).

ADDRESSES: The Final PEIS is available for download from *www.regulations.gov* FIRSTNET–FPEIS–2017–0001. A CD of this document is also available for viewing at public libraries (see Chapter 16 of the Final PEIS for the complete distribution list).

FOR FURTHER INFORMATION CONTACT: For more information on the Final PEIS, contact Amanda Goebel Pereira, NEPA Coordinator, First Responder Network Authority, National Telecommunications and Information Administration, U.S. Department of Commerce, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192.

SUPPLEMENTARY INFORMATION: The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 256 (codified at 47 U.S.C. 1401 *et seq.*)) (the ''Act'') created and authorized FirstNet to take all actions necessary to ensure the building, deployment, and operation of an interoperable, nationwide public safety broadband network (''NPSBN'') based on a single, national network architecture. The Act meets a longstanding and critical national infrastructure need, to create a single, nationwide network that will, for the first time, allow police officers, fire fighters, emergency medical service professionals, and other public safety entities to effectively communicate with each other across agencies and jurisdictions. The NPSBN is intended to enhance the ability of the public safety community to perform more reliably, effectively, and safely; increase situational awareness during an emergency; and improve the ability of the public safety community to effectively engage in those critical activities.

The National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) (''NEPA'') requires federal agencies to undertake an assessment of environmental effects of their proposed actions prior to making a final decision and implementing the action. NEPA requirements apply to any federal project, decision, or action that may have a significant impact on the quality of the human environment. NEPA also establishes the Council on Environmental Quality (''CEQ''), which issued regulations implementing the procedural provisions of NEPA (see 40 CFR parts 1500–1508). Among other considerations, CEQ regulations at 40 CFR 1508.28 recommend the use of *tiering* from a ''broader environmental impact statement (such as a national program or policy statements) with subsequent narrower statements or environmental analysis (such as regional or basin wide statements or ultimately site-specific statements) incorporating by reference the general discussions and concentrating solely on the issues specific to the statement subsequently prepared.''

Due to the geographic scope of FirstNet (all 50 states, the District of Columbia, and five territories) and the diversity of ecosystems potentially traversed by the project, FirstNet has elected to prepare five regional PEISs. The five PEISs are divided into the East, Central, West, South, and Non-Contiguous Regions. The Non-Contiguous Region consists of Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. The Final PEIS analyzes potential impacts of the deployment and operation of the NPSBN on the natural and human environment in the Non-Contiguous

Region, in accordance with FirstNet's responsibilities under NEPA.

Now that this PEIS has been completed and once a Record of Decision (ROD) has been signed, the proposed FirstNet projects can begin to submit the site-specific environmental documentation to determine if the proposed project has been adequately evaluated in the PEIS or whether it instead warrants a Categorical Exclusion, an Environmental Assessment, or an Environmental Impact Statement.

Dated: June 27, 2017.

Amanda Goebel Pereira,

NEPA Coordinator, First Responder Network Authority.

[FR Doc. 2017–13795 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–805]

Stainless Steel Bar From Spain: Final Results of Antidumping Duty Administrative Review; 2015–2016

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

SUMMARY: On March 3, 2017, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on stainless steel bar (SSB) from Spain. The period of review (POR) is March 1, 2015, through February 29, 2016. The review covers one producer/exporter of the subject merchandise, Gerdau Aceros Especiales Europa, S.L. (Gerdau).

DATES: Effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Mullen or Ian Hamilton, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5260 or (202) 482–4798, respectively.

Scope of the Order

The merchandise covered by the order is SSB products. The merchandise subject to this order is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7222.10.00, 7222.11.00, 7222.19.00, 7222.20.00, and 7222.30.00. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[1]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the Issues and Decision Memorandum.[2] A list of the issues that parties raised and to which we responded is attached to this notice as an Appendix. 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 (CRU), room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties, we have not made changes to the *Preliminary Results.* Because mandatory respondent Gerdau has failed to provide requested information, we will continue to apply adverse facts available (AFA) to this respondent, in accordance with sections 776(a) and (b) of the Act and 19 CFR 351.308. For further discussion, *see* the Issues and Decision Memorandum.

Final Results of the Review

We determine that, for the period of March 1, 2015, through February 29, 2016, the following weighted-average dumping margin exists:

Exporter/producer	Weighted-average dumping margin (percent)
Gerdau Aceros Especiales Europa, S.L.	62.85

[1] The HTSUS numbers provided in the scope changed since the publication of the order. *See Amended Final Determination and Antidumping Duty Order: Stainless Steel Bar from Spain,* 60 FR 11656 (March 2, 1995).

[2] *See* Memorandum, ''Certain Stainless Steel Bar from Spain: Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review; 2015–2016,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Duty Assessment

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.

In accordance with the Department's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Gerdau for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Gerdau will be the rate established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 25.77 percent, the all-others rate established in the investigation.[3] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement

[3] *See Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Bar from Spain,* 59 FR 66931 (December 28, 1994).

could result in the Secretary's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/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 this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: June 26, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum:

1. Summary
2. List of Comments
3. Background
4. Scope of the Order
5. Discussion of Comments
   a. Whether the Department Should Have Granted Gerdau's Untimely Extension Request
   b. Whether the Department Should Apply AFA to Gerdau
6. Recommendation

[FR Doc. 2017–13793 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–051]

Certain Hardwood Plywood Products From the People's Republic of China: Postponement of Final Determination of Sales at Less Than Fair Value Investigation

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

SUMMARY: The Department of Commerce (the Department) is postponing the deadline for issuing the final determination in the less-than-fair-value (LTFV) investigation of certain hardwood plywood products (hardwood plywood) from the People's Republic of China (PRC) until November 6, 2017, and is extending the provisional measures from a four-month period to a period of not more than six months.

DATES: Effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Mullen or Amanda Brings, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5260 or (202) 482–3927, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2016, the Department of Commerce (the Department) initiated a LTFV investigation of imports of hardwood plywood from the PRC.[1] The period of investigation is April 1, 2016, through September 30, 2016. On June 23, 2017, the Department published its *Preliminary Determination* in this LTFV investigation of hardwood plywood from the PRC.[2]

Postponement of Final Determination

Section 735(a)(2) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(2) provide that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by the exporters or producers who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Further, 19 CFR 351.210(e)(2) requires that such postponement requests by exporters be accompanied by a request for extension of provisional measures from a four-month period to a period of not more than six months, in accordance with section 733(d) of the Act.

On June 14, 2017, Linyi Chengen Import And Export Co., Ltd. and Shandong Dongfang Bayley Wood Co., Ltd., the mandatory respondents in this investigation, requested that the Department fully extend the deadline for the final determination, and extend the application of the provisional measures from a four-month period to a period of not more than six months.[3]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination was affirmative; (2) the request was made by the exporters and producers who account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, the Department is postponing the final determination until no later than 135 days after the date of the publication of the *Preliminary Determination,* and extending the provisional measures from a four-month period to a period of not more than six months. Accordingly, the Department will issue its final determination no later than November 6, 2017.[4]

This notice is issued and published pursuant to 19 CFR 351.210(g).

Dated: June 26, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–13792 Filed 6–29–17; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–810, A–583–815

Welded ASTM A–312 Stainless Steel Pipe From South Korea and Taiwan: Continuation of Antidumping Duty Orders

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

SUMMARY: The Department of the Commerce (the Department) and the International Trade Commission (the ITC) have determined that revocation of the antidumping duty (AD) orders on

[1] *See Certain Hardwood Plywood Products From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 81 FR 91125 (December 16, 2016).

[2] *See Certain Hardwood Plywood Products from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, in Part,* 82 FR 28629 (June 23, 2017) (*Preliminary Determination*).

[3] *See* Letter from Linyi Chengen Import And Export Co., Ltd. and Shandong Dongfang Bayley Wood Co., Ltd., ''Hardwood Plywood Products from the People's Republic of China: Request for Extension of Final Determination,'' dated June 14, 2017.

[4] Postponing the final determination to 135 days after the publication of the *Preliminary Determination* would place the deadline on Sunday, November 5, 2017. The Department's practice dictates that 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).

certain welded stainless steel pipe from South Korea and Taiwan would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States. Therefore, the Department is publishing a notice of continuation for these AD orders.

DATES: June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, 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) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On December 30, 1992, the Department of Commerce (the Department) published the antidumping duty orders on welded ASTM A–312 stainless steel pipe (WSSP) from South Korea and Taiwan. On November 1, 2016, the Department published a notice of initiation of its fourth five-year (sunset) reviews of the antidumping duty orders on welded ASTM A–312 stainless steel pipe from South Korea and Taiwan.[1]

As a result of these sunset reviews, the Department determined that revocation of the AD orders on WSSP from South Korea and Taiwan would likely lead to continuation or recurrence of dumping, and therefore, notified the U.S. International Trade Commission (ITC) of the magnitude of the margins likely to prevail should these orders be revoked.[2]

On May 17, 2017, the ITC published its determination that revocation of the AD orders on WSSP from South Korea and Taiwan would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time, pursuant to section 751(C) of the Act.[3]

Scope of the Orders

The merchandise subject to the antidumping duty orders is welded austenitic stainless steel pipe that meets the standards and specifications set forth by the American Society for Testing and Materials (ASTM) for the welded form of chromium-nickel pipe designated ASTM A–312. The merchandise covered by the scope of the orders also includes austenitic welded stainless steel pipes made according to the standards of other nations which are comparable to ASTM A–312.

WSSP is produced by forming stainless steel flat-rolled products into a tubular configuration and welding along the seam. WSSP is a commodity product generally used as a conduit to transmit liquids or gases. Major applications for steel pipe include, but are not limited to, digester lines, blow lines, pharmaceutical lines, petrochemical stock lines, brewery process and transport lines, general food processing lines, automotive paint lines, and paper process machines. Imports of WSSP are currently classifiable under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7306.40.5005, 7306.40.5015, 7306.40.5040, 7306.40.5062, 7306.40.5064, and 7306.40.5085.[4] Although these subheadings include both pipes and tubes, the scope of the antidumping duty orders is limited to welded austenitic stainless steel pipes. The HTSUS subheadings are provided for convenience and customs purposes. However, the written description of the scope of the orders is dispositive.

Continuation of the Orders

As a result of the determinations by the Department and the ITC that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping duty orders on welded ASTM A–312 stainless steel pipe from South Korea and Taiwan.

U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of these orders will be the date of publication in the **Federal Register** of the notice of continuation of the antidumping duty orders on WSSP from Korea and Taiwan. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the sunset reviews of these orders not later than 30 days prior to the fifth anniversary of the effective date of continuation.

These sunset reviews and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: June 27, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–13988 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Initiation of Five-Year (''Sunset'') Reviews,* 81 FR 75808 (November 1, 2016).

[2] *See Welded ASTM A–312 Stainless Steel Pipe From South Korea and Taiwan: Final Results of the Expedited Fourth Sunset Reviews of the Antidumping Duty Orders,* 82 FR 12798 (March 7, 2017) and accompanying Issues and Decision Memorandum.

[3] *See Certain Welded Stainless Steel Pipe From Korea and Taiwan; Determinations,* 94 FR 22674 (May 17, 2017).

[4] HTS 7306.40.5065 previously listed in the scope of the order for this product is no longer a valid reporting number, having been replaced by 7306.40.6052 and 7306.40.6054 as of January 1, 1996.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813, A–301–803, A–549–833]

Citric Acid and Certain Citrate Salts From Belgium, Colombia, and Thailand: Initiation of Less-Than-Fair-Value Investigations

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

DATES: Effective June 22, 2017.

FOR FURTHER INFORMATION CONTACT: Paul Stolz at (202) 482–4474 (Belgium); Stephanie Moore at (202) 482–3692 (Colombia); and George McMahon at (202) 482–1167 (Thailand), AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On June 2, 2017, the Department of Commerce (the Department) received antidumping duty (AD) petitions (the Petitions) concerning imports of citric acid and certain citrate salts (citric acid) from Belgium, Colombia, and Thailand, filed in proper form on behalf of Archer Daniels Midland Company (ADM); Cargill Incorporated (Cargill); and Tate & Lyle Ingredients America LLC (Tate & Lyle) (collectively, the petitioners).[1] The Petitions were accompanied by a countervailing duty (CVD) petition concerning citric acid from Thailand.[2] The petitioners are domestic producers of citric acid.[3]

On June 7, 12, 14, and 16, 2017, the Department requested additional information and clarification of certain areas of the Petitions.[4] The petitioners

[1] *See* ''Petitions for the Imposition of Antidumping and Countervailing Duties on Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand,'', dated June 2, 2017 (the Petitions).

[2] *Id.*

[3] *See* Volume I of the Petitions, at 2.

[4] *See* Country-specific letters to the petitioners from the Department concerning supplemental

filed responses to these requests on June 9, 14, 15, and 16, 2017, respectively.[5]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that imports of citric acid and certain citrate salts from Belgium, Colombia, and Thailand, are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioners supporting their allegations.

The Department finds that the petitioners filed these Petitions on behalf of the domestic industry because the petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the AD investigations that the petitioners are requesting.[6]

Period of Investigation

Because the Petitions were filed on June 2, 2017, the period of investigation (POI) for each investigation is April 1, 2016, through March 31, 2017.[7]

Scope of the Investigations

The product covered by these investigations is citric acid and certain citrate salts from Belgium, Colombia, and Thailand. For a full description of the scope of these investigations, *see* the ''Scope of the Investigations,'' in the Appendix to this notice.

Comments on Scope of the Investigations

During our review of the Petitions, the Department issued questions to, and received responses from, the petitioners pertaining to the proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.[8]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determinations. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on July 12, 2017, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information (also limited to public information), must be filed by 5:00 p.m. ET on July 24, 2017, which is the next business day after 10 calendar days after the initial comments. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently believes that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. As stated above, all such comments must be filed on the records of each of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[9] An electronically filed document must be received successfully in its entirety by the time and date when it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

The Department will provide interested parties an opportunity to comment on the appropriate physical characteristics of citric acid to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the merchandise under consideration in order to report the relevant costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe citric acid, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on July 12, 2017, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, must be filed by 5:00 p.m. ET on July 24, 2017. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the records of the Belgium, Colombia, and Thailand less-than-fair-value investigations.

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questions on each of the country-specific records, dated June 7, 2017; *see also* Letter to the petitioners from the Department concerning supplemental questions on general issues, dated June 12, 2017; Memorandum to the File ''Antidumping Duty Petition for the Imposition of Antidumping Duties on Citric Acid and Certain Citrate Salts from Belgium and Thailand. Re: Overhead and Profit,'' dated June 14, 2017.

[5] *See* Country-specific amendments to the Petitions on each of the country-specific records; *see also* Letter from the Petitioners, ''Antidumping Duty Investigation of Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Petitioners' Responses to Supplemental Questions—Volume I,'' dated June 14, 2017 (General Issues Supplement).

[6] *See* the ''Determination of Industry Support for the Petitions'' section below.

[7] *See* 19 CFR 351.204(b)(1).

[8] *See* General Issues Supplement, at 1–4.

[9] *See* 19 CFR 351.303 (for general filing requirements); *see also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[10] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[11]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petitions).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that citric acid, as defined in the scope, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[12]

In determining whether the petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the Appendix to this notice. To establish industry support, the petitioners provided their own production of the domestic like product in 2016.[13] The petitioners state that they represent the totality of the domestic industry producing citric acid; therefore, the Petitions are supported by 100 percent of the U.S. industry.[14]

Our review of the data provided in the Petitions, the General Issues Supplement, and other information readily available to the Department indicates that the petitioners have established industry support for the Petitions.[15] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[16] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[17] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[18] Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that the petitioners filed the Petitions on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the AD investigations that they are requesting that the Department initiate.[19]

Allegations and Evidence of Material Injury and Causation

The petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[20]

The petitioners contend that the industry's injured condition is illustrated by reduced market share; underselling and price suppression or depression; lost sales and revenues; adverse impact on the domestic industry's production, capacity utilization, and U.S. shipments; and declines in financial performance.[21] We have assessed the allegations and supporting evidence regarding material

[10] *See* section 771(10) of the Act.

[11] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[12] For a discussion of the domestic like product analysis, *see* Antidumping Duty Investigation Initiation Checklist: Citric Acid and Certain Citrate Salts from Belgium (Belgium AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand (Attachment II); Antidumping Duty Investigation Initiation Checklist: Citric Acid and Certain Citrate Salts from Colombia (Colombia AD Initiation Checklist), at Attachment II; and Antidumping Duty Investigation Initiation Checklist: Citric Acid and Certain Citrate Salts from Thailand (Thailand AD Initiation Checklist), at Attachment II. These checklists are dated concurrently with, and hereby adopted by, this notice and on file electronically *via* ACCESS. Access to documents filed *via* ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[13] *See* Volume I of the Petitions, at Exhibit I–13.

[14] *Id.,* at 2–3 and Exhibits I–1 and I–2; *see also* General Issues Supplement, at 1, 7 and Attachments 1 and 3.

[15] *See* Belgium AD Initiation Checklist, Colombia AD Initiation Checklist, and Thailand AD Initiation Checklist, at Attachment II.

[16] *See* section 732(c)(4)(D) of the Act; *see also* Belgium AD Initiation Checklist, Colombia AD Initiation Checklist, and Thailand AD Initiation Checklist, at Attachment II.

[17] *See* Belgium AD Initiation Checklist, Colombia AD Initiation Checklist, and Thailand AD Initiation Checklist, at Attachment II.

[18] *Id.*

[19] *Id.*

[20] *See* Volume I of the Petitions, at 21–22 and Exhibit I–12.

[21] *See* Volume I of the Petitions, at 17–32 and Exhibits I–7 and I–9—I–15; *see also* General Issues Supplement, at 1, 7 and Attachments 1 and 3.

injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[22]

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less than fair value upon which the Department based its decision to initiate investigations of imports of citric acid from Belgium, Colombia and Thailand. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the country-specific initiation checklists.[23]

Export Price

For Belgium, Colombia, and Thailand, the petitioners based export price (EP) on two methodologies: (1) POI average unit values (AUVs), and (2) transaction-specific AUVs for shipments of citric acid from the three countries. The first uses official U.S. import statistics to determine the AUV of imports of citric acid under the relevant Harmonized Tariff Schedule of the United States (HTSUS) subheading during the POI. The second involves matching individual shipments of goods identified in the U.S. Customs and Border Protection's (CBP's) Automated Manifest System (AMS) to individual entries of citric acid in the official U.S. import statistics for specific months and specific ports.[24] Because the AUVs are based on the reported customs values and include freight and brokerage and handling to the port of exportation, the petitioners adjusted the customs values for foreign brokerage and handling and foreign inland freight costs to arrive at an ex-factory price.[25]

Normal Value Based on Home Market Prices

For Belgium, Colombia, and Thailand, the petitioners provided home market price information obtained through market research for citric acid produced in, and offered for sale in, each of these countries.[26] For all three of these countries, the petitioners provided a declaration from a market researcher for the price information.[27] Where applicable, the petitioners made certain deductions from the prices for movement or other expenses, consistent with the terms of sale.[28]

For Belgium and Thailand, the petitioners provided information indicating that sales of citric acid in the home market were made at prices below the cost of production (COP) and, as a result, calculated NV based on constructed value (CV).[29] [30] For further discussion of COP and NV based on CV, see below.

Normal Value Based on Constructed Value

Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (COM); selling, general and administrative (SG&A) expenses; financial expenses; and packing expenses.

For Belgium, the petitioners calculated COM during the POI, adjusted for known differences based on information available to the petitioners.[31] The petitioners valued material inputs using publicly available data for the prices of these inputs, where possible.[32] The petitioners valued labor inputs for citric acid using publicly-available data multiplied by the product-specific usage rates.[33] To calculate the factory overhead rate, the petitioners relied on the fiscal year end (FYE) December 31, 2015, audited financial statements of Belgian citric acid producer, S.A. Citrique Belge N.V. (Citrique Belge).[34] To calculate the SG&A plus financial expense rate, the petitioners also relied on the FYE December 31, 2015, audited financial statements of Citrique Belge.[35]

Because certain home market prices fell below COP, pursuant to sections 773(a)(4), 773(b), and 773(e) of the Act, as noted above, the petitioners calculated NVs based on CV.[36] Pursuant to section 773(e) of the Act, CV consists of the COM, SG&A, financial expenses, packing expenses, and profit. The petitioners calculated CV using the same COP described above, adding an amount for profit.[37] The petitioners calculated the profit rate based on the fiscal year 2016 financial statements of one of the U.S. citric acid producers.[38] The profit rate was applied to the corresponding total COM, SG&A, and financial expenses calculated above to derive CV.[39]

For Thailand, the petitioners calculated COM using the same surrogate as was used for Belgium during the POI, adjusted for known differences based on information available to the petitioners.[40] The petitioners valued material inputs using publicly available data for the prices of these inputs, where possible. The petitioners valued labor and energy inputs for citric acid using publicly available data multiplied by the product-specific usage rates.[41] To calculate the SG&A plus financial expense rate, the petitioners relied on the FYE December 31, 2015, audited financial statements for COFCO Biochemical (Thailand) Co., Ltd. (COFCO), Niran Thailand Co., Ltd. (Niran), Sunshine Biotech International Co., Ltd. (Sunshine), and Thai Citric Acid Co., Ltd. (Thai Citric). The rate was computed based on the FYE December 31, 2015, SG&A (including other income and expenses), plus financial and investment income and financial costs.[42] Because none of the four companies' financial statements contained any factory overhead detail, the petitioners relied on the audited financial statements for Ajinomoto Company (Thailand) Ltd. (Ajinomoto) for the fiscal year 2015–2016, *i.e.,* April 2015 through March 2016. Ajinomoto is a producer of lysine and monosodium glutamate, both of which are bio-fermentation products produced using processes similar to those used for citric acid production.[43]

[22] *See* Belgium AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand (Attachment III); Colombia AD Initiation Checklist, at Attachment III; and Thailand AD Initiation Checklist, at Attachment III.

[23] *See* Belgium AD Initiation Checklist; Colombia AD Initiation Checklist; and Thailand AD Initiation Checklist.

[24] *See* Belgium AD Initiation Checklist; Colombia AD Initiation Checklist; and Thailand AD Initiation Checklist.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *See* Belgium AD Initiation Checklist and Thailand AD Initiation Checklist.

[30] Under the Trade Preferences Extension Act of 2015, numerous amendments to the AD and CVD laws were made. *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015). *See also Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*). The amendments to sections 771(15), 773, 776, and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to these AD investigations. *See Applicability Notice,* 80 FR at 46794–95. The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[31] *See* Belgium AD Initiation Checklist.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *See* Belgium AD Initiation Checklist.

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] *See* Thailand AD Initiation Checklist.

[41] *Id.*

[42] *Id.*

[43] *Id.*

Because certain home market prices fell below COP, pursuant to sections 773(a)(4), 773(b), and 773(e) of the Act, as noted above, the petitioners also calculated NV based on CV.[44] Pursuant to section 773(e) of the Act, CV consists of the COM, SG&A, financial expenses, packing expenses, and profit. To calculate CV, we used the same COM calculated by the petitioners, plus the revised SG&A, and financial expense figures to compute the COP.[45] To calculate the profit rate, we relied on the 2015 financial statements for a Thai producer which was then applied to the total of material, labor and energy (MLE), factory overhead costs, SG&A and financial expenses.[46]

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of citric acid from Belgium, Colombia, and Thailand are being, or are likely to be, sold in the United States at less than fair value. Based on comparisons of EP to NV, in accordance with sections 772 and 773(a) of the Act, the estimated dumping margin(s) for citric acid are as follows: 41.18 to 49.46 percent for Colombia,[47] and 4.6 percent to 40.0 percent for Thailand.[48] Based on comparisons of EP to CV in accordance with sections 772 and 773(e) of the Act, the estimated dumping margins are as follows: 15.80 percent to 62.13 percent for Belgium,[49] and 15.18 percent to 39.98 percent for Thailand.[50]

Initiation of Less-Than-Fair-Value Investigations

Based upon the examination of the AD Petitions, we find that the Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of citric acid from Belgium, Colombia, and Thailand are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

Based on information from independent sources, the petitioners identified one company in Belgium, one company in Colombia, and four companies in Thailand, as producers/exporters of citric acid.[51] With respect to Thailand, following standard practice in AD investigations involving market-economy countries, the Department intends to review U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate HTSUS numbers listed with the ''Scope of the Investigations,'' in the Appendix below. If it determines that, due to the large number of exporters or producers, it cannot individually examine each company based upon the Department's resources, then the Department will select respondents based on the CBP data. We also intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO. Comments regarding the CBP data and respondent selection should be submitted seven calendar days after the placement of the CBP data on the record of the investigation. Parties wishing to submit rebuttal comments should submit those comments five calendar days after the deadline for the initial comments.

Although the Department normally relies on the number of producers/exporters identified in the petition and/or import data from CBP to determine whether to select a limited number of producers/exporters for individual examination in AD investigations, the Petitions identified only one company as a producer/exporter of citric acid in Belgium, Citrique Belge,[52] and one company in Colombia, Sucroal, S.A.[53] We currently know of no additional producers/exporters of merchandise under consideration from these countries, and the petitioners provided information from independent sources as support.[54] Accordingly, the Department intends to examine all known producers/exporters in the investigations for Belgium and Colombia (*i.e.,* the companies cited above for each respective investigation). Parties wishing to comment on respondent selection for Belgium and Colombia must do so within five days of the publication of this notice in the **Federal Register**.

Comments for the above-referenced investigations must be filed electronically using ACCESS. An electronically-filed document must be received successfully in its entirety by 5:00 p.m. ET by the dates noted above. We intend to finalize our decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the governments of Belgium, Colombia, and Thailand via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter (as named in the Petitions), consistent with 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of citric acid from Belgium, Colombia, and/or Thailand are materially injuring or threatening material injury to a U.S. industry.[55] A negative ITC determination for any country will result in the investigation being terminated with respect to that country.[56] Otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Parties should review the regulations prior to

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *See* Colombia AD Initiation Checklist.

[48] *See* Thailand AD Initiation Checklist.

[49] *See* Belgium AD Initiation Checklist.

[50] *See* Thailand AD Initiation Checklist.

[51] *See* Volume I of the Petitions at Exhibit I–5.

[52] *Id.; see also* Volume II of the Petitions, at 1 and Exhibit II–1.

[53] *See* Volume I of the Petitions at Exhibit I–5, and Volume III of the Petitions, at 1 and Exhibit III–1.

[54] See Volume I of the Petitions at Exhibit I–5.

[55] *See* section 733(a) of the Act.

[56] *Id.*

submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under Part 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[57] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[58] The Department intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

[57] *See* section 782(b) of the Act.

[58] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to section 777(i) of the Act and 19 CFR 351.203(c).

Dated: June 22, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Investigations

The merchandise covered by these investigations includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

[FR Doc. 2017–13823 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–857]

Certain Softwood Lumber Products From Canada: Preliminary Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The Department of Commerce (the Department) preliminarily determines that certain softwood lumber products (softwood lumber) from Canada is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2015, through September 30, 2016.

DATES: Effective June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Stephen Bailey or Thomas Martin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0193 or (202) 482–3936, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on December 22, 2016.[1] On April 14, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now June 23, 2017.[2] On April 13, 2017, the Department preliminarily determined that critical circumstances exist.[3] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary

[1] *See Certain Softwood Lumber Products from Canada: Initiation of Less-Than-Fair-Value Investigation,* 81 FR 93892 (December 22, 2016) (*Initiation Notice*).

[2] *See Certain Softwood Lumber Products from Canada: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 82 FR 18421 (April 19, 2017).

[3] *See Antidumping and Countervailing Duty Investigations of Certain Softwood Lumber Products From Canada: Preliminary Determinations of Critical Circumstances,* 82 FR 19219 (April 26, 2017) (*Preliminary Critical Circumstances Determinations*).

Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is softwood lumber from Canada. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[5] the *Initiation Notice* set aside a period of time for interested parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Scope Decision.[7] The Department is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice. Furthermore, the Department has proposed additional changes to the scope language and has invited further input from the interested parties.[8] Finally, the Department has responded to the Committee Overseeing Action for Lumber International Trade Investigations or Negotiations' (the petitioner's) request to amend the petition to exclude Atlantic Lumber Board (ALB)-certified lumber from the scope of the antidumping and countervailing duty (CVD) investigations.[9]

Particular Market Situation (PMS) Allegation

On May 15, 2017, the petitioner alleged that certain particular market situations exist within the Canadian lumber industry.[10] The petitioner's PMS allegation asserts that the Government of Canada (GOC) increased the demand for lumber byproducts by establishing and supporting bioenergy, electricity and stumpage programs. The petitioner alleges that the demand created by these programs caused an increase in the production of byproducts, which, in turn, increased the production of lumber. The petitioner asserts that the only remedy for addressing the distortion to the cost of production (COP) caused by the GOC's interventions is to deny the byproduct offset to COP claimed by the respondents.

Specifically, regarding bioenergy programs, the petitioner alleges that the GOC has increased the demand for lumber byproducts by encouraging the development of energy from biomass, including wood chips from lumber. Regarding electricity, the petitioner alleges that the GOC has instituted certain energy initiatives that allow sawmills and consumers of lumber byproducts to either reduce or offset their electricity costs. The petitioner alleges these actions have decreased the electricity costs associated with producing lumber and lumber byproducts, which, in turn, distorts the COP of lumber producers. For stumpage, the petitioner alleges that lumber producers are able to obtain a steady supply of subsidized logs, which then enables them to meet the increased demand for byproducts.

The Department finds that the petitioner's presentation and discussion of the bioenergy, electricity and stumpage programs promoted by the GOC, substantiates the petitioner's allegations that such interventions and subsidies may have distorted the byproduct market and consequently the COP of lumber producers. The Department intends to further investigate and analyze the alleged distortions to COP raised by the petitioner in its PMS allegation. We intend to issue a schedule to provide deadlines for interested parties to submit further factual information related to the PMS allegation. We also intend to issue a supplemental questionnaire to all interested parties to obtain additional information to aid us in the analysis of the petitioner's PMS allegation. For further discussion of this matter, refer to the PMS Allegation Memorandum.[11]

Methodology

The Department is conducting this investigation in accordance with section 731 of the Act. The Department has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances, in Part

As explained above, on April 13, 2017, the Department preliminarily determined that critical circumstances exist for all-others and do not exist for Canfor, Resolute, Tolko, and West Fraser. For a full description of the methodology and results of the Department's critical circumstances analysis, *see* the *Preliminary Critical Circumstances Determinations.*

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination the Department shall determine an

[4] *See* Preliminary Decision Memorandum.

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice.*

[7] *See* Memorandum, ''Certain Softwood Lumber Products from Canada: Scope Decision,'' dated concurrently with this preliminary determination (Scope Decision).

[8] *Id.*

[9] *See* Memorandum, ''Decision Memorandum for Exclusion of Certain Softwood Lumber Products Certified By the Atlantic Lumber Board in the Antidumping Duty and Countervailing Duty Investigations of Certain Softwood Lumber Products from Canada,'' dated June 23, 2017 (ALB Decision Memorandum) where the Department preliminarily excluded from the scope softwood lumber products certified by the ALB as being first produced in the Provinces of Newfoundland and Labrador, Nova Scotia, or Prince Edward Island from logs harvested in these three provinces. However, as noted in the ALB Decision Memorandum, U.S. Customs and Border Protection (CBP) has not yet begun collecting ALB certifications, and the Department needs assurance that CBP will have a system in place to collect the certifications before we permit these products to be excluded. Thus, CBP will continue to suspend liquidation of entries of merchandise subject to the CVD investigation, and we will instruct CBP to begin suspension of liquidation of merchandise subject to this investigation. If there are no changes to the preliminary decision to exclude this merchandise, at the final determination, the Department will instruct CBP to stop suspension of liquidation of the merchandise subject to the exclusion and to refund cash deposits.

[10] *See* Letter from the petitioner to the Secretary, regarding ''Certain Softwood Lumber Products from Canada: Particular Market Situation Regarding Respondents' Cost of Production,'' dated May 15, 2017 (PMS allegation).

[11] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Certain Softwood Lumber Products from Canada: Particular Market Situation Allegation,'' dated concurrently with this memorandum (PMS Allegation Memorandum).

estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, the Department calculated estimated weighted-average dumping margins for Canfor, Resolute, Tolko, and West Fraser, none of which are zero, *de minimis,* or based entirely on facts otherwise available. The Department calculated the all-others' rate using a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's business proprietary data for the merchandise under consideration.[12]

Preliminary Determination

The Department preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margins (percent)
Canfor Corporation, Canadian Forest Products Ltd., and Canfor Wood Products Marketing Ltd[13]	7.72
Resolute FP Canada Inc[14]	4.59
Tolko Marketing and Sales Ltd. and Tolko Industries Ltd[15]	7.53
West Fraser Mills Ltd[16]	6.76
All-Others	6.87

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, the Department will direct CBP to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. As discussed in *Preliminary Critical Circumstances Determinations,* the Department preliminarily found that critical circumstances exist for imports of subject merchandise shipped by the companies subject to the all-others rate. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of shipments of subject merchandise from companies subject to the all-others rate that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

Disclosure

The Department intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, the Department intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[17] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

[12] For a complete analysis of the data, please *see* the All-Others Calculation Memorandum dated concurrently with this notice.

[13] The Department preliminarily determines that Canfor, Canadian Forest Products Ltd., and Canfor Wood Products Marketing Ltd. are a single entity. *See* Memorandum, ''Antidumping Duty Investigation of Certain Softwood Lumber from Canada: Tolko Industries Ltd. and Tolko Marketing and Sales Ltd. Preliminary Affiliation and Collapsing Memorandum,'' dated June 23, 2017.

[14] The Department preliminarily determines that Resolute and Resolute Growth Canada Inc. (Resolute Growth), Abitibi-LP Engineered Wood Inc. (Abitibi-LP), Abitibi-LP Engineered Wood II Inc. (Abitibi-LP II), Forest Products Mauricie LP (Mauricie), Produits Forestiers Petit-Paris Inc. (Petit-Paris), Société en commandite Scierie Opitciwan (Opitciwan), 9265–7030 Québec Inc. (9265–7030 Inc.), are a single entity. *See* Memorandum, ''Antidumping Duty Investigation of Certain Softwood Lumber from Canada: Resolute FP Canada Inc. Preliminary Affiliation and Collapsing Memorandum,'' dated June 23, 2017.

[15] The Department preliminarily determines that Tolko and Gilbert Smith Forest Products Ltd. are a single entity. *See* Memorandum, ''Antidumping Duty Investigation of Certain Softwood Lumber from Canada: Tolko Industries Ltd. and Tolko Marketing and Sales Ltd. Preliminary Affiliation and Collapsing Memorandum,'' dated June 23, 2017.

[16] The Department preliminarily determines that West Fraser and Blue Ridge Lumber Inc. (Blue Ridge), Manning Forest Products Ltd. (Manning), and Sundre Forest Products Inc. (Sundre) are a single entity. *See* Memorandum, ''Antidumping Duty Investigation of Certain Softwood Lumber from Canada: West Fraser Mills Ltd. Preliminary Affiliation and Collapsing Memorandum,'' dated June 23, 2017.

[17] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 733(f) of the Act, the Department intends to notify the International Trade Commission (ITC) of its preliminary affirmative determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

We intend to issue and publish this notice in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: June 23, 2017.

Ronald Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is softwood lumber, siding, flooring and certain other coniferous wood (softwood lumber products). The scope includes:

- Coniferous wood, sawn, or chipped lengthwise, sliced or peeled, whether or not planed, whether or not sanded, or whether or not finger-jointed, of an actual thickness exceeding six millimeters.
- Coniferous wood siding, flooring, and other coniferous wood (other than moldings and dowel rods), including strips and friezes for parquet flooring, that is continuously shaped (including, but not limited to, tongued, grooved, rebated, chamfered, V-jointed, beaded, molded, rounded) along any of its edges, ends, or faces, whether or not planed, whether or not sanded, or whether or not end-jointed.
- Coniferous drilled and notched lumber and angle cut lumber.
- Coniferous lumber stacked on edge and fastened together with nails, whether or not with plywood sheathing.
- Components or parts of semi-finished or unassembled finished products made from subject merchandise that would otherwise meet the definition of the scope above.

Softwood lumber product imports are generally entered under Chapter 44 of the Harmonized Tariff Schedule of the United States (HTSUS).[18] This chapter of the HTSUS covers ''Wood and articles of wood.'' Softwood lumber products that are subject to this investigation are currently classifiable under the following ten-digit HTSUS subheadings in Chapter 44: 4407.10.01.01; 4407.10.01.02; 4407.10.01.15; 4407.10.01.16; 4407.10.01.17; 4407.10.01.18; 4407.10.01.19; 4407.10.01.20; 4407.10.01.42; 4407.10.01.43; 4407.10.01.44; 4407.10.01.45; 4407.10.01.46; 4407.10.01.47; 4407.10.01.48; 4407.10.01.49; 4407.10.01.52; 4407.10.01.53; 4407.10.01.54; 4407.10.01.55; 4407.10.01.56; 4407.10.01.57; 4407.10.01.58; 4407.10.01.59; 4407.10.01.64; 4407.10.01.65; 4407.10.01.66; 4407.10.01.67; 4407.10.01.68; 4407.10.01.69; 4407.10.01.74; 4407.10.01.75; 4407.10.01.76; 4407.10.01.77; 4407.10.01.82; 4407.10.01.83; 4407.10.01.92; 4407.10.01.93; 4409.10.05.00; 4409.10.10.20; 4409.10.10.40; 4409.10.10.60; 4409.10.10.80; 4409.10.20.00; 4409.10.90.20; 4409.10.90.40; and 4418.99.10.00.

Subject merchandise as described above might be identified on entry documentation as stringers, square cut box-spring-frame components, fence pickets, truss components, pallet components, flooring, and door and window frame parts. Items so identified might be entered under the following ten-digit HTSUS subheadings in Chapter 44: 4415.20.40.00; 4415.20.80.00; 4418.99.90.05; 4418.99.90.20; 4418.99.90.40; 4418.99.90.95; 4421.91.70.40; and 4421.91.97.80.

Although these HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these investigations is dispositive.

The scope of the order excludes the following items:

U.S.-origin lumber shipped to Canada for processing and imported into the United States is excluded from the scope of the investigations if the processing occurring in Canada is limited to one or more of the following: (1) Kiln drying; (2) planing to create smooth-to-size board; or (3) sanding.

Box-spring frame kits are excluded if they contain the following wooden pieces—two side rails, two end (or top) rails and varying numbers of slats. The side rails and the end rails must be radius-cut at both ends. The kits must be individually packaged and must contain the exact number of wooden components needed to make a particular box spring frame, with no further processing required. None of the components exceeds 1″ in actual thickness or 83″ in length.

Radius-cut box-spring-frame components, not exceeding 1″ in actual thickness or 83″ in length, ready for assembly without further processing are excluded. The radius cuts must be present on both ends of the boards and must be substantially cut so as to completely round one corner.

[18] Throughout this document, all references to the HTSUS are based on the HTSUS as it exists at *https://hts.usitc.gov/current.*

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2017–13794 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–549–834]

Citric Acid and Certain Citrate Salts From Thailand: Initiation of Countervailing Duty Investigation

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

DATES: Effective June 22, 2017.

FOR FURTHER INFORMATION CONTACT: John Conniff at (202) 482–1009, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petition

On June 2, 2017, the Department of Commerce (the Department) received a countervailing duty (CVD) petition concerning imports of citric acid and

certain citrate salts (citric acid) from Thailand,[1] filed in proper form on behalf of Archer Daniels Midland Company (ADM); Cargill Incorporated (Cargill); and Tate & Lyle Ingredients Americas LLC (Tate & Lyle) (collectively, the petitioners). The Petition was accompanied by antidumping duty (AD) petitions concerning imports of citric acid from Belgium, Colombia and Thailand.[2] The petitioners are domestic producers of citric acid.[3]

On June 7, and June 12, 2017, the Department requested additional information and clarification of certain areas of the Petition.[4] The petitioners filed responses to these requests on June 9, and June 14, 2017, respectively.[5]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that imports of citric acid from Thailand received countervailable subsidies from Thai government authorities within the meaning of sections 701 and 771(5) of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 702(b)(1) of the Act, for those alleged programs on which we are initiating a CVD investigation, the Petition alleged the elements of a subsidy and provided information reasonably available to the petitioners supporting the allegations.

The Department finds that the petitioners filed the Petition on behalf of the domestic industry because the petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the CVD investigation that the petitioners are requesting.[6]

[1] *See* ''Petitions for the Imposition of Antidumping and Countervailing Duties on Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand,'' dated June 2, 2017, at Volume V (Petition).

[2] *See* Petition, Volumes II–IV.

[3] *See* Volume I of the Petitions, at 2.

[4] *See* Letter to the petitioners from the Department, ''Petition for the Imposition of Countervailing Duties on Imports of Citric Acid and Certain Citrate Salts from Thailand: Supplemental Questions,'' dated June 7, 2017; *see also* Letter to the petitioners from the Department concerning supplemental questions on general issues, dated June 12, 2017.

[5] *See* Letter from the petitioners, ''Petitioners' Responses to Supplemental Questions,'' dated June 9, 2017; *see also* Letter from the petitioners, ''Antidumping Duty Investigation of Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Petitioners' Responses to Supplemental Questions—Volume I,'' dated June 14, 2017 (General Issues Supplement).

[6] *See* ''Determination of Industry Support for the Petitions'' section, below.

Period of Investigation

Because the Petition was filed on June 2, 2017, the period of investigation (POI) is January 1, 2016, through December 31, 2016.[7]

Scope of the Investigation

The product covered by this investigation is citric acid and certain citrate salts from Thailand. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' in the Appendix to this notice.

Comments on Scope of the Investigation

During our review of the Petition, the Department issues questions to, and received responses from, the petitioners pertaining to the proposed scope to ensure that the scope language in the Petition would be an accurate reflection of the products for which the domestic industry is seeking relief.[8]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope). The Department will consider all comments received from parties and, if necessary, will consult with parties prior to the issuance of the preliminary determinations. If scope comments include factual information (*see* 19 CFR 351.102(b)(21)), all such factual information should be limited to public information. In order to facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on July 12, 2017, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information (also limited to public information), must be filed by 5:00 p.m. ET on July 24, 2017, which is the next business day after 10 calendar days after the initial comments. All such comments must be filed on the records of this investigation and each of the concurrent AD investigations.

The Department requests that any factual information the parties consider relevant to the scope of this investigation be submitted during this time period. However, if a party subsequently believes that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact the Department and request permission to submit the additional information. As stated above, all such comments must be filed on the records of this investigation and each of the concurrent AD investigations.

[7] *See* 19 CFR 351.204(b)(2).

[8] *See* General Issues Supplement, at 1–4.

Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[9] An electronically-filed document must be received successfully in its entirety by the time and date it is due. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to section 702(b)(4)(A)(i) of the Act, the Department notified representatives of the Royal Thai Government (RTG) of the receipt of the Petition. Also, in accordance with section 702(b)(4)(A)(ii) of the Act, the Department provided representatives of the RTG with an opportunity for consultations with respect to the Petition. Consultations with the RTG were held at the Department's main building on June 14, 2017. The invitation letter and the memorandum regarding these consultations are on file electronically *via* ACCESS.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic

[9] *See* 19 CFR 351.303 (for general filing requirements); *see also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx,* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[10] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[11]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the Petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that citric acid, as defined in the scope, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[12]

In determining whether the petitioners have standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the Appendix to this notice. To establish industry support, the petitioners provided their own production of the domestic like product in 2016.[13] The petitioners state that they represent the totality of the domestic industry producing citric acid; therefore, the Petition is supported by 100 percent of the U.S. industry.[14]

Our review of the data provided in the Petition, the General Issues Supplement, and other information readily available to the Department indicates that the petitioners have established industry support for the Petition.[15] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[16] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[17] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[18] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

The Department finds that the petitioners filed the Petition on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act, and they have demonstrated sufficient industry support with respect to the CVD investigation they are requesting the Department to initiate.[19]

Injury Test

Because Thailand is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from Thailand materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[20] In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent. The petitioners also demonstrate that subject imports from Thailand, which has been designated as developing country under section 771(36)(A) of the Act, exceed the negligibility threshold of four percent.[21]

The petitioners contend that the industry's injured condition is illustrated by reduced market share; underselling and price suppression or depression; lost sales and revenues; adverse impact on the domestic industry's production, capacity utilization, and U.S. shipments; and declines in financial performance.[22] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported

[10] *See* section 771(10) of the Act.

[11] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[12] For a discussion of the domestic like product analysis, *see* Countervailing Duty Investigation Initiation Checklist: Citric Acid and Certain Citrate Salts from Thailand (Thailand CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand (Attachment II). This checklist is dated concurrently with this notice and on file electronically *via* ACCESS. Access to documents filed *via* ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[13] *See* Volume I of the Petition, at Exhibit I–13.

[14] *Id.,* at 2–3 and Exhibits I–1 and I–2; *see also* General Issues Supplement, at 1, 7 and Attachments 1 and 3.

[15] *See* Thailand CVD Initiation Checklist, at Attachment II.

[16] *See* section 702(c)(4)(D) of the Act; *see also* Thailand CVD Initiation Checklist, at Attachment II.

[17] *See* Thailand CVD Initiation Checklist, at Attachment II.

[18] *Id.*

[19] *Id.*

[20] *See* Volume I of the Petition, at 21–22 and Exhibit I–12.

[21] *Id.*

[22] *See* Volume I of the Petition, at 17–32 and Exhibits I–7 and I–9—I–15.

by adequate evidence, and meet the statutory requirements for initiation.[23]

Initiation of CVD Investigation

Section 702(b)(1) of the Act requires the Department to initiate a CVD investigation whenever an interested party files a CVD petition on behalf of an industry that: (1) Alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to the petitioners supporting the allegations.

The petitioners allege that producers/exporters of citric acid in Thailand benefit from countervailable subsidies bestowed by their government. The Department examined the Petition and finds that it complies with the requirements of section 702(b)(1) of the Act. Therefore, in accordance with section 702(b)(1) of the Act, we are initiating this CVD investigation to determine whether manufacturers, producers, and/or exporters of citric acid in Thailand receive countervailable subsidies from Thai government authorities.

Under the Trade Preferences Extension Act of 2015, numerous amendments to the AD and CVD law were made.[24] The amendments to sections 776 and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to this CVD investigation.[25]

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on all nine alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* the Thailand CVD Initiation Checklist. A public version of the initiation checklist is available on ACCESS.

In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Respondent Selection

Based on information from independent sources, the petitioners identified four companies in Thailand as producers/exporters of citric acid.[26] Following standard practice in CVD investigations, the Department intends to review U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate HTSUS numbers listed in the ''Scope of the Investigation,'' in the Appendix, below. If the Department determines that, due to the large number of producers or exporters, it cannot individually examine each company based on the Department's resources, then the Department will select respondents based on the CBP data. We intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO. Comments regarding the CBP data and respondent selection should be submitted seven calendar days after the placement of the CBP data on the record of the investigation. Parties wishing to submit rebuttal comments should submit those comments five calendar days after the deadline for the initial comments.

Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the RTG *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each known exporter (as named in the Petition), consistent with 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of citric acid from Thailand are materially injuring, or threatening material injury to, a U.S. industry.[27] A negative ITC determination will result in the investigation being terminated.[28] Otherwise, this investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Parties should review the regulations prior to submitting factual information in this investigation.

Extension of Time Limits Regulation

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to

[23] *See* Thailand CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand (Attachment III).

[24] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015). *See also, Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*).

[25] *See Applicability Notice,* 80 FR at 46794–95.

[26] *See* Petitions, Volume I at 30–31.

[27] *See* section 703(a)(2) of the Act.

[28] *See* section 703(a)(1) of the Act.

submitting factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[29] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.[30] The Department intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act.

Dated: June 22, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise covered by this investigation includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

[FR Doc. 2017–13824 Filed 6–29–17; 8:45 am]

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[29] *See* section 782(b) of the Act.

[30] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*''); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–863]

Honey From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Review and Notice of Amended Final Results of Review Pursuant to Court Decision

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

SUMMARY: The Department of Commerce (the Department) is notifying the public that the Court of International Trade's (CIT's or the Court's) final judgment in this case is not in harmony with the Department's final results of review and is, therefore, amending the final dumping duty margin for one reviewed company.

DATES: *Effective Date:* June 10, 2017.

FOR FURTHER INFORMATION CONTACT: John Drury, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0195.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2001, the Department published an amended final determination of sales at less than fair value, and an antidumping duty order, on honey from the People's Republic of China (PRC).[1] As part of the Department's amended final determination, the Department made affirmative critical circumstances determinations for Zhejiang Native Produce and Animal By-Products Import & Export Corp., a.k.a. Zhejiang Native Produce and Animal By-Products Import and Export Group Corporation (Zhejiang), and certain other firms.[2]

On January 20, 2003, the Department initiated an administrative review of the antidumping duty order on honey from the PRC covering the period February 10, 2001, through November 30, 2002.[3] In the administrative review, the Department determined normal value using a factors of production (FOP) methodology, pursuant to section 773(c) of the Tariff Act of 1930, as amended (the Act) and selected India as the primary surrogate country from which to derive surrogate values.

On May 5, 2004, the Department published the *Final Results.*[4] On June 10, 2004, the Department published the *Amended Final Results,* which corrected certain ministerial errors.[5] In the *Amended Final Results,* the Department corrected the antidumping duty margin for respondent Zhejiang from 68.35 percent to 67.70 percent *ad valorem.*

Zhejiang challenged the *Final Results* and *Amended Final Results* before the CIT. On November 19, 2004, the Department amended the record of the proceeding to add 11 documents that were not included in the original

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order; Honey from the People's Republic of China,* 66 FR 63670 (December 10, 2001) (*Amended Final Determination and Order*).

[2] *Id.,* at 63672.

[3] *See Initiation of Antidumping and Countervailing Administrative Review and Requests for Revocation in Part,* 68 FR 3009 (January 22, 2003) (*Initiation Notice*).

[4] *See Honey from the People's Republic of China: Final Results of First Antidumping Duty Administrative Review,* 69 FR 25060 (May 5, 2004), and the accompanying ''Issues and Decision Memorandum for the Final Results of the First Administrative Review of the Antidumping Order on Honey from the People's Republic of China,'' dated April 28, 2004 (Decision Memorandum) (collectively, *Final Results*).

[5] *See Honey from the People's Republic of China: Amended Final Results of First Antidumping Duty Administrative Review,* 69 FR 32494 (June 10, 2004) (*Amended Final Results*).

record,[6] but were identified as part of a Freedom of Information Act (FOIA) request filed by Zhejiang.

At the same time that Zhejiang challenged the Department's *Final Results* as amended, litigation concerning the Department's final determination of critical circumstances in the less than fair value investigation of honey from the PRC ensued.[7] In light of the fact that the POR for the first administrative review was, in part, based on the Department's finding of critical circumstances in the investigation, the CIT stayed further action pending the outcome of the litigation relating to the investigation. The CIT affirmed the Department's finding on remand of no critical circumstances on June 18, 2013.[8]

On August 3, 2015, the CIT remanded this case to the Department. Specifically, the Court: (1) Granted the Department's request for a voluntary remand to reconsider the issues related to the surrogate value for raw honey; (2) remanded the issue of the selection of the appropriate financial statements; and (3) requested that the Department recalculate Zhejiang's dumping margin to reflect the different POR resulting from the decision in *Zhejiang Native Produce & Animal By-Products Import & Export Corp.* v. *United States,* Court No. 02–00057.

The Department released a draft redetermination on December 31, 2015, and invited comments from parties.[9] The Department released a final redetermination on February 10, 2016.[10] In the Final Redetermination, consistent with the Court's instructions and after a review of information on the record and comments from interested parties, the Department found that a change in the surrogate value for raw honey was not warranted and that a change in the financial statements for calculating surrogate values for factory overhead, selling, general and administrative expenses, and profit, was also not warranted. In addition, the Department removed sales corresponding to the critical circumstances period and recalculated the antidumping duty margin. Specifically, the Department calculated a margin of 67.06 percent *ad valorem* for Zhejiang's sales of honey from the PRC for the period of May 11, 2001, to November 30, 2002.[11]

On June 1, 2017, the CIT sustained the Department's Final Redetermination in its entirety.[12]

Timken Notice

In its decision in *Timken,*[13] as clarified by *Diamond Sawblades,*[14] the United States Court of Appeals for the Federal Circuit (CAFC) held that, pursuant to sections 516A(c) and (e) of the Act, the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's June 1, 2017, judgment in *Zhejiang III,* sustaining the Department's decision in the Final Redetermination to re-calculate the dumping margin for Zhejiang from 67.70 percent to 67.06 percent, constitutes a final decision of the court that is not in harmony with the *Amended Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Accordingly, the Department will issue liquidation instructions to U.S. Customs and Border Protection (CBP) to liquidate entries of honey from the PRC exported to or imported into the United States by Zhejiang at the rate of 67.06 percent *ad valorem* pending expiration of the period to appeal or, if appealed, pending a final and conclusive court decision.

Second Amended Final Results

Because there is now a final court decision, the Department amends the *Amended Final Results* with respect to the dumping margin of Zhejiang. The revised weighted-average dumping margin for Zhejiang during the period May 11, 2001, to November 30, 2002, is as follows:

Exporter	Weighted-average dumping margin (percent)
Zhejiang Native Produce & Animal By-Products Import & Export Corp.	67.06

In the event the Court's ruling is not appealed, or if appealed and upheld by the CAFC, the Department will instruct CBP to assess antidumping duties on entries of the subject merchandise exported by Zhejiang using the revised assessment rate calculated by the Department in the *Final Redetermination.*

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: June 23, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–13791 Filed 6–29–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF282

Endangered and Threatened Species; Listing and Recovery Priority Guidelines

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

ACTION: Notice of availability; extension of comment period.

SUMMARY: On May 31, 2017, we, NMFS, published a notice of availability to revise the Recovery Plan Preparation and Implementation Priorities and Recovery Plans contained in the 1990 Listing and Recovery Priority Guidelines. We opened a public comment period that lasted through June 30, 2017. We received several requests to extend the public comment period. Thus, we are extending the period through August 28, 2017.

DATES: Comments on the proposed revision must be received by close of business on August 28, 2017.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0020 by either of the following methods:

- *Federal e-Rulemaking Portal:* Go to *www.regulations.gov/*

[6] *See* Letter to All Interested Parties, dated October 21, 2015, at Attachment I, citing to Amended Public Record 121–131, Ct. No. 04–268; *see also Amendment to Administrative Record in Zhejiang Native Produce and Animal By-Products Import and Export Corp* v. *United States,* Court No 04–00268, dated November 19, 2004.

[7] *See Zhejiang Native Produce & Animal By-Products Import & Export Corp.* v. *United States,* Court No. 02–00057, 25 ITRD (BNA) 2394 (CIT November 21, 2003); 26 ITRD (BNA) 2320 (CIT August 26, 2004).

[8] *See Zhejiang Native Produce & Animal By-Products Import & Export Corp.* v. *United States,* 2013 WL 2996235, Slip Op. 13–76 (CIT 2013).

[9] *See* Letter to All Interested Parties, dated December 31, 2015 (Draft Redetermination).

[10] *See Zhejiang Native Produce & Animal By-Products Import & Export Corp.* v. *United States,* Court No. 04–00268, dated February 10, 2016 (Final Redetermination).

[11] *See* Final Redetermination at 29–30.

[12] *See Zhejiang Native Produce & Animal By-Products Import & Export Corp.* v. *United States,* Court No. 04–00268, dated June 1, 2017 (*Zhejiang III*).

[13] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[14] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

#!docketDetail;D=NOAA-NMFS-2017-0020. Click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Therese Conant, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: You must submit comments by one of the above methods to ensure that we receive, document, and consider them. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *http://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

SUPPLEMENTARY INFORMATION:

Background

Section 4(f) of the Endangered Species Act (ESA) (16 U.S.C. 1533(f)) requires the Secretary to develop recovery plans for all species listed pursuant to the ESA, unless he/she finds that such a plan will not promote the recovery of the species. Section 4(h) of the ESA requires the Secretary to establish a system for developing and implementing, on a priority basis, recovery plans under Section 4(f). We finalized guidance for prioritizing recovery plan development and implementation on June 15, 1990 (55 FR 24296). However, through our application of the Recovery Plan Preparation and Implementation Priorities and Recovery Plans (see parts 'B' and 'C' 55 FR 24296; June 15, 1990), we have determined that the guidelines contain vague definitions and lack sufficient detail regarding factors that should be considered when evaluating threats and recovery potential. For these reasons, we published, on May 31, 2017 (82 FR 24944), proposed revisions to the Recovery Plan Preparation and Implementation Priorities and Recovery Plan parts of the 1990 Listing and Recovery Priority Guidelines. We solicited comments on the proposed revision to be submitted by June 30, 2017. On June 14 and June 16, 2017, we received requests to extend the public comment period by an additional 30 days and 90 days, respectively. Thus, we are extending the public comment period through August 28, 2017. Previously submitted comments do not need to be resubmitted.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: June 26, 2017.

Catherine Marzin,

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

[FR Doc. 2017–13714 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF425

Endangered and Threatened Species; Initiation of 5-Year Review for the North Pacific Right Whale

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

ACTION: Notice of initiation of 5-year review; request for information.

SUMMARY: NMFS announces a 5-year review of the North Pacific right whale (*Eubalaena japonica*) under the Endangered Species Act of 1973 (ESA), as amended. A 5-year review must be based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information on these whales that has become available since the last status review in 2012.

DATES: To allow us adequate time to conduct this review, we must receive your information no later than July 31, 2017. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0046, by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0046,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Jon Kurland, Assistant Regional Administrator for Protected Resources, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Verena Gill, NMFS Alaska Region, (907) 271–1937, *verena.gill@noaa.gov.*

SUPPLEMENTARY INFORMATION: Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every five years. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species currently under active review. This notice announces our active review of North Pacific right whales, currently listed as endangered. To ensure that the 5-year review is complete and based on the best available scientific and commercial information, we are soliciting new information from the public, governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of North Pacific right whales. Categories of requested information include: (1) Species biology and demographics (population trends, distribution, abundance, genetics, etc.); (2) habitat conditions (amount, distribution, suitability, quality, etc.); (3) conservation measures that have been implemented that benefit the species; (4) status and trends of threats; and (5) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the list of threatened and endangered species, and improved analytical methods, if any. Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for these whales.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: June 26, 2017.

Catherine Marzin,

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

[FR Doc. 2017–13701 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

Under 44 U.S.C. 3506(e) and 13 U.S.C. Section 9, the U.S. Census Bureau is seeking comments on revisions to the confidentiality pledge it provides to its respondents under Title 13, United States Code, Section 9. These revisions are required by the passage and implementation of provisions of the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. 1501 note), which require the Secretary of Homeland Security to provide Federal civilian agencies' information technology systems with cybersecurity protection for their Internet traffic. More details on this announcement are presented in the **SUPPLEMENTARY INFORMATION** section below. The previous notice for public comment, titled ''Agency Information Collection Activities; Request for Comments; Revision of the Confidentiality Pledge under Title 13 United States Code, Section 9'' was published in the **Federal Register** on December 23, 2016 (Vol. 81, No. 247, pp. 94321–94324), allowing for a 60 day comment period. The Census Bureau received two comments, which are addressed within this notice.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 2015, Congress passed the Federal Cybersecurity Enhancement Act of 2015 (the Act) (6 U.S.C. 1501 note). The Act requires the Department of Homeland Security to deploy for use by other agencies a program with the ''capability to detect cybersecurity risks in network traffic transiting or traveling to or from an agency information system.'' [1] The Act requires each agency to ''apply and continue to utilize the capabilities to all information traveling between an agency information system and any information system other than an agency information system.'' [2] The DHS program is known as EINSTEIN, and DHS currently operates version 3A (E3A). Importantly, the Act provides that DHS may use the information collected through EINSTEIN ''only to protect information and information systems from cybersecurity risks.'' [3] The Act does not authorize DHS to use information collected through EINSTEIN for any other purposes, including law enforcement purposes.

In response to the passage of the Act, the Census Bureau considered whether it should revise its confidentially pledge. The Census Bureau's Center for Survey Measurement (CSM) joined the interagency Statistical Community of Practice and Engagement (SCOPE) Confidentiality Pledge Revision Subcommittee, which developed and evaluated the revision to the confidentiality pledge language. SCOPE and CSM conducted remote and in-person cognitive testing of the potential revised confidentiality pledge. The Census Bureau based its revised confidentiality pledge on the results of these tests. The revised confidentiality pledge utilizes the language the Census Bureau determined would best communicate the essential information to respondents while not negatively affecting response rates. The following is the revised statistical confidentiality pledge for the Census Bureau's data collections:

The U.S. Census Bureau is required by law to protect your information. The Census Bureau is not permitted to publicly release your responses in a way that could identify you. Per the Federal Cybersecurity Enhancement Act of 2015, your data are protected from cybersecurity risks through screening of the systems that transmit your data.

On December 23, 2016, the Census Bureau requested comments on the revised confidentiality pledge. During the public comment period, the Census Bureau received two comments from the Asian Americans Advancing Justice (AAJC) and American-Arab Anti-Discrimination Committee (ADC).

II. Comments and Responses

In response to the Census Bureau's revised confidentiality pledge, AAJC and the ADC provided comments and suggestions to the Census Bureau. These comments and suggestions, along with the Census Bureau's responses are below.

1. The AAJC and the ADC both expressed concerns about the effect of the revised confidentiality pledge on the accuracy of the results of the Census Bureau's survey.

Response: The Census Bureau is committed to collecting the most complete and accurate data. The Census Bureau takes the collection and protection of respondent information very seriously and has since the first Decennial Census in 1790. As a statistical agency committed to ensuring the collection and publication of accurate data, the Census Bureau continually conducts extensive research and testing to inform census and survey design. This research and testing confirms key technologies, outreach and promotional strategies, data collection methods, and management and response processes to allow the Census Bureau to maximize response rates and ensure the accuracy of the data collected. We also uphold a strong data stewardship culture to ensure that any decisions we make will fulfill our legal and ethical obligations to respect your privacy and protect the confidentiality of your information. The revised confidentiality pledge utilizes language that the Census Bureau determined, after cognitive testing, would not negatively affect response rates, and hence the accuracy of the survey results.

2. The ''ADC has serious concerns on the ability of [DHS] to . . . access . . . people's personal information on the server.''

Response: E3A does not provide DHS with access to a respondent's personal information. E3A does not currently decrypt respondent information or scan data at rest on Census Bureau information systems. Moreover, the Act limits the use of any information collected, stating that the DHS may use information obtained through activities authorized under this section ''only to protect information and information systems from cybersecurity risks.'' (6 U.S.C. 151(c)(3)).

EINSTEIN also provides greater protection for the Census Bureau's information and information systems than would otherwise exist. EINSTEIN enables DHS to detect cyber threat indicators traveling or transiting to or from one agency's information system, and to share those indicators with other agencies, thereby making all agencies' information systems more secure. The necessity of providing DHS limited access to such information—information which DHS can only use for cybersecurity purposes—is not only required by the Federal Cybersecurity Enhancement Act, but has a net positive impact of the security of information respondents provide to the Census Bureau.

3. The ADC is concerned that ''there is a lack of safeguards in place on who has access to information through EINSTEIN.''

Response: In addition to the safeguards contained in the Act, the Census Bureau works with DHS to protect information DHS may access through EINSTEIN. These additional safeguards cover the collection, retention, use, and disclosure of information. The safeguards also

[1] Sec. 230(b)(1)(A) of the Homeland Security Act of 2002 (6 U.S.C. 151(b)(1)(A)), as added by section 223((a)(6) of the Federal Cybersecurity Enhancement Act of 2015.

[2] Section 223 (b)(1)(A) (6 U.S.C. 151 note) of the Federal Cybersecurity Enhancement Act of 2015.

[3] Section 230(c)(3) of the Homeland Security Act of 2002 (6 U.S.C. 151(c)(3)), as added by section 223(a)(6) of the Federal Cybersecurity Enhancement Act of 2015.

include notification and reporting requirements in the unlikely event that any unauthorized access, use, or dissemination of any Census Bureau information would occur.

To reiterate, the information at issue is not a respondent's personal information, rather, it is cyber threat information. E3A does not provide DHS with access to a respondent's personal information. E3A does not currently decrypt respondent information or scan data at rest on Census Bureau information systems.

4. The ADC is concerned that the revised confidentiality pledge ''raises flags on improper use of such information.''

Response: The Act limits DHS's use of information collected pursuant to the Act to the protection of ''information and information systems from cybersecurity risks.'' To be clear, DHS's use of the information for any other purpose would be unlawful.

5. The AAJC suggests that the protections contained in Title 13 and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), both of which limit the use and disclosure of information collected, should control the information at issue.

Response: Pursuant to the Act, each agency must ''apply and continue to utilize the capabilities to all information traveling between an agency information system and any information system other than an agency information system.'' Congress authorized that, notwithstanding the protections previously afforded to information by other laws, such as Title 13, for the purpose of protecting agency information systems from cyber attacks, DHS may access information transiting and traveling to or from an agency information system. Census Bureau employees remain subject to the penalties contained in Title 13, including a federal prison sentence of up to five years and a fine of up to $250,000, or both.

6. The AAJC suggests that either the Census Bureau employees ''perform Einstein 3A functions for Census Bureau internet traffic'' or that ''DHS employees monitoring Census Bureau internet traffic under Einstein 3A take the current Title 13 confidentiality pledge.''

Response: The Act provides DHS access to network traffic transiting or traveling to or from the Census Bureau's information systems, notwithstanding the protections previously afforded to information by other laws, such as Title 13. The Act also requires each agency to ''apply and continue to utilize the capabilities to all information traveling between an agency information system and any information system other than an agency information system.''

In addition to the safeguards contained in the Act, the Census Bureau works with DHS to safeguard respondent information. These additional safeguards cover the collection, retention, use, and disclosure of information. The safeguards also include notification and reporting requirements that would apply in the unlikely event that any unauthorized access, use, or dissemination of any Census Bureau information would occur.

III. Data

Agency: U.S. Census Bureau, Department of Commerce.

Title: Revision of the Confidentiality Pledge under Title 13 United States Code, Section 9.

OMB Control Number: 0607–0993.

Form Number(s): None.

Affected Public: All survey respondents to Census Bureau data collections.

Legal Authority: 44 U.S.C. 3506(e) and 13 U.S.C. Section 9.

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

IV. Request for Comments

Comments are invited on the necessity and efficacy of the Census Bureau's revised confidentiality pledge above. Comments submitted in response to this notice will become a matter of public record. Comments should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Dated: June 27, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer on behalf of the Department of Commerce.

[FR Doc. 2017–13778 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF304

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meetings; Cancellation

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

ACTION: Notice of change of schedule for SEDAR 56 South Atlantic Black Sea Bass Assessment Webinars.

SUMMARY: The SEDAR 56 assessment of the South Atlantic stock of black seabass will consist of a series webinars. Due to changes to the schedule for the stock assessment, webinars scheduled for Thursday, July 20, 2017 and Wednesday, August 16, 2017 have been cancelled. See **SUPPLEMENTARY INFORMATION.**

DATES: This notice serves to cancel the previously scheduled July 20, 2017 and August 16, 2017 webinars.

ADDRESSES: *SEDAR address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on March 29, 2017 (82 FR 15495).

The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. The product of the SEDAR webinar series will be a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

During its June 2017 meeting, the South Atlantic Fishery Management

Council made a decision to change the terminal year for the data used on the stock assessment for the South Atlantic black sea bass stock. The decision affects the schedule for the stock assessment and consequently, the scheduled webinars as previously published in the **Federal Register**. An updated schedule will be published once the details are available.

Dated: June 26, 2017.

Jeffrey N. Lonergan,

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

[FR Doc. 2017–13662 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process on Internet of Things Security Upgradability and Patching

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene a virtual meeting of a multistakeholder process on Internet of Things Security Upgradability and Patching on July 18, 2017. This is the fourth in a series of meetings. For information on prior meetings, see Web site address below.

DATES: The virtual meeting will be held on July 18, 2017, from 2:00 p.m. to 4:30 p.m., Eastern Time. See **SUPPLEMENTARY INFORMATION** for details.

ADDRESSES: This is a virtual meeting. NTIA will post links to online content and dial-in information on the multistakeholder process Web site at *https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security.*

FOR FURTHER INFORMATION CONTACT: Allan Friedman, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone: (202) 482–4281; email: *afriedman@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs: (202) 482–7002; email: *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background: In March of 2015 the National Telecommunications and Information Administration issued a Request for Comment to ''identify substantive cybersecurity issues that affect the digital ecosystem and digital economic growth where broad consensus, coordinated action, and the development of best practices could substantially improve security for organizations and consumers.'' [1] We received comments from a range of stakeholders, including trade associations, large companies, cybersecurity startups, civil society organizations and independent computer security experts.[2] The comments recommended a diverse set of issues that might be addressed through the multistakeholder process, including cybersecurity policy and practice in the emerging area of Internet of Things (IoT).

In a separate but related matter in April 2016, NTIA, the Department's Internet Policy Task Force, and its Digital Economy Leadership Team sought comments on the benefits, challenges, and potential roles for the government in fostering the advancement of the Internet of Things.'' [3] Over 130 stakeholders responded with comments addressing many substantive issues and opportunities related to IoT.[4] Security was one of the most common topics raised. Many commenters emphasized the need for a secure lifecycle approach to IoT devices that considers the development, maintenance, and end-of-life phases and decisions for a device.

After reviewing these comments, NTIA announced that the next multistakeholder process on cybersecurity would be on IoT security upgradability and patching.[5] The first meeting of a multistakeholder process on this topic was held on October 19, 2016.[6] A second, virtual meeting of this process was held on January 31, 2017,[7] and a third meeting was held on April 26, 2017.[8]

The matter of patching vulnerable systems is now an accepted part of cybersecurity.[9] Unaddressed technical flaws in systems leave the users of software and systems at risk. The nature of these risks varies, and mitigating these risks requires various efforts from the developers and owners of these systems. One of the more common means of mitigation is for the developer or other maintaining party to issue a security patch to address the vulnerability. Patching has become more commonly accepted, even for consumers, as more operating systems and applications shift to visible reminders and automated updates. Yet as one security expert notes, this evolution of the software industry has yet to become the dominant model in IoT.[10]

To help realize the full innovative potential of IoT, users need reasonable assurance that connected devices, embedded systems, and their applications will be secure. A key part of that security is the mitigation of potential security vulnerabilities in IoT devices or applications through patching and security upgrades.

The ultimate objective of the multistakeholder process is to foster a market offering more devices and systems that support security upgrades through increased consumer awareness and understanding. Enabling a thriving market for patchable IoT requires common definitions so that manufacturers and solution providers

[1] U.S. Department of Commerce, Internet Policy Task Force, Request for Public Comment, Stakeholder Engagement on Cybersecurity in the Digital Ecosystem, 80 FR 14360, Docket No. 150312253–5253–01 (Mar. 19, 2015), *available at: https://www.ntia.doc.gov/files/ntia/publications/cybersecurity_rfc_03192015.pdf.*

[2] NTIA has posted the public comments received at *https://www.ntia.doc.gov/federal-register-notice/2015/comments-stakeholder-engagement-cybersecurity-digital-ecosystem.*

[3] U.S. Department of Commerce, Internet Policy Task Force, Request for Public Comment, Benefits, Challenges, and Potential Roles for the Government in Fostering the Advancement of the Internet of Things, 81 FR 19956, Docket No 160331306–6306–01 (April 5, 2016), *available at: https://www.ntia.doc.gov/federal-register-notice/2016/rfc-potential-roles-government-fostering-advancement-internet-of-things.*

[4] NTIA has posted the public comments received at *https://www.ntia.doc.gov/federal-register-notice/2016/comments-potential-roles-government-fostering-advancement-internet-of-things.*

[5] NTIA, *Increasing the Potential of IoT through Security and Transparency* (Aug. 2, 2016), *available at: https://www.ntia.doc.gov/blog/2016/increasing-potential-iot-through-security-and-transparency.*

[6] NTIA, Notice of Multistakeholder Process on Internet of Things Security Upgradability and Patching Open Meeting (Sept. 15, 2016), *available at: https://www.ntia.doc.gov/federal-register-notice/2016/10192016-meeting-notice-msp-iot-security-upgradability-patching.*

[7] NTIA, Notice of Multistakeholder Process on Internet of Things Security Upgradability and Patching Open Meeting (April 11, 2017), *available at https://www.ntia.doc.gov/federal-register-notice/2017/notice-04262017-meeting-multistakeholder-process-internet-things.*

[8] NTIA, Notice of Multistakeholder Process on Internet of Things Security Upgradability and Patching Open Meeting (Sept. 15, 2016), *available at: https://www.ntia.doc.gov/federal-register-notice/2016/10192016-meeting-notice-msp-iot-security-upgradability-patching.*

[9] *See, e.g.,* Murugiah Souppaya and Karen Scarfone, *Guide to Enterprise Patch Management Technologies, Special Publication 800–40 Revision 3,* National Institute of Standards and Technology, NIST SP 800–40 (2013) *available at: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-40r3.pdf.*

[10] Bruce Schneier, *The Internet of Things Is Wildly Insecure—And Often Unpatchable,* Wired (Jan. 6, 2014), *available at: https://www.schneier.com/blog/archives/2014/01/security_risks_9.html.*

have shared visions for security, and consumers know what they are purchasing. Currently, no such common, widely accepted definitions exist, so many manufacturers struggle to effectively communicate to consumers the security features of their devices. This is detrimental to the digital ecosystem as a whole, as it does not reward companies that invest in patching and it prevents consumers from making informed purchasing choices.

Stakeholders have identified four distinct work streams that could help foster better security across the ecosystem, and focused their efforts in four working groups addressing both technical and policy issues.[11] The main objectives of the July 18, 2017, meeting are to share progress from the working groups and hear feedback from the broader stakeholder community. Stakeholders will also discuss how the outputs of the different work streams can complement each other. More information about stakeholders' work is available at: *https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security.*

Time and Date: NTIA will convene a virtual meeting of the multistakeholder process on Internet of Things Security Upgradability and Patching on July 18, 2017, from 2:00 p.m. to 4:30 p.m., Eastern Time. The meeting date and time are subject to change. Please refer to NTIA's Web site, *https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security,* for the most current information.

Place: This is a virtual meeting. NTIA will post links to online content and dial-in information on the multistakeholder process Web site at *https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security.*

Other Information: The meeting is open to the public and the press. There will be an opportunity for stakeholders viewing the webcast to participate remotely in the meeting through a moderated conference bridge, including polling functionality. Access details for the meeting are subject to change. Requests for a transcript of the meeting or other auxiliary aids should be directed to Allan Friedman at (202) 482–4281 or *afriedman@ntia.doc.gov* at least seven (7) business days prior to each meeting. Please refer to NTIA's Web site, *https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security,* for the most current information.

Dated: June 27, 2017.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2017–13775 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–60–P

[11] Documents shared by working group stakeholders are *available at: https://www.ntia.doc.gov/other-publication/2016/multistakeholder-process-iot-security.*

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Community Broadband Workshop

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA), through the BroadbandUSA program, will hold a Technical Assistance Workshop to share information and help communities build their broadband capacity and utilization. The workshop will present in-depth sessions on planning and funding broadband infrastructure projects. The session on planning will explore effective business and partnership models. The session on funding will explore available funding options and models, including federal funding.

DATES: The Technical Assistance Workshop will be held on August 21, 2017, from 8:30 a.m. to 12:30 p.m., Central Daylight Time.

ADDRESSES: The meeting will be held in Des Moines, Iowa at the Des Moines Public Library, 1000 Grand Avenue, Des Moines, IA 50309.

FOR FURTHER INFORMATION CONTACT: Giselle Sanders, National Telecommunications and Information Administration, U.S. Department of Commerce, Room 4889, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–7971; email: *gsanders@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email: *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION: NTIA's BroadbandUSA program provides expert advice and field-proven tools for assessing broadband adoption, planning new infrastructure, and engaging a wide range of partners in broadband projects. BroadbandUSA convenes workshops on a regular basis to bring stakeholders together to discuss ways to improve broadband policies, share best practices, and connect communities to other federal agencies and funding sources for the purpose of expanding broadband infrastructure and adoption throughout America's communities. The Des Moines workshop will explore two specific topics for broadband infrastructure: Planning and funding.

The Des Moines workshop will feature subject matter experts from NTIA's BroadbandUSA broadband program. The first session will explore key elements required for planning successful broadband projects. The second session will explore funding models, including federal programs that fund broadband infrastructure projects.

The Des Moines workshop will be open to the public. Pre-registration is requested, and space is limited. NTIA will ask registrants to provide their first and last names and email addresses for both registration purposes and to receive any updates on the workshop. If capacity for the meeting is reached, NTIA will maintain a waiting list and will inform those on the waiting list if space becomes available. Meeting updates, changes in the agenda, if any, and relevant documents will also be available on NTIA's Web site at *https://www2.ntia.doc.gov/notice-08212017-workshop.*

The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as language interpretation or other ancillary aids, are asked to notify Giselle Sanders at the contact information listed above at least five (5) business days before the meeting.

Dated: June 27, 2017.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2017–13777 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Commerce Spectrum Management Advisory Committee Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a public meeting of the Commerce Spectrum Management Advisory Committee (Committee). The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information and

the National Telecommunications and Information Administration (NTIA) on spectrum management policy matters.

DATES: The meeting will be held on August 15, 2017, from 8:00 a.m. to 11:00 a.m., Mountain Daylight Time (MDT).

ADDRESSES: The meeting will be held at the Renaissance Boulder Flatiron Hotel, 500 Flatiron Boulevard, Broomfield, CO 80021. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4600, Washington, DC 20230 or emailed to *dreed@ntia.doc.gov.*

FOR FURTHER INFORMATION CONTACT: David J. Reed, Designated Federal Officer, at (202) 482–5955 or *dreed@ntia.doc.gov;* and/or visit NTIA's Web site at *https://www.ntia.doc.gov/category/csmac.*

SUPPLEMENTARY INFORMATION:

Background: The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information on needed reforms to domestic spectrum policies and management in order to: License radio frequencies in a way that maximizes public benefits; keep wireless networks as open to innovation as possible; and make wireless services available to all Americans. *See* Charter at *https://www.ntia.doc.gov/files/ntia/publications/csmac_charter-2017.pdf.* This Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and is consistent with the National Telecommunications and Information Administration Act, 47 U.S.C. 904(b). The Committee functions solely as an advisory body in compliance with the FACA. For more information about the Committee visit: *https://www.ntia.doc.gov/category/csmac.*

Matters to Be Considered: The Committee provides advice to the Assistant Secretary to assist in developing and maintaining spectrum management policies that enable the United States to maintain or strengthen its global leadership role in the introduction of communications technology, services, and innovation; thus expanding the economy, adding jobs, and increasing international trade, while at the same time providing for the expansion of existing technologies and supporting the country's homeland security, national defense, and other critical needs of government missions. NTIA will post a detailed agenda on its Web site, *https://www.ntia.doc.gov/category/csmac,* prior to the meeting. To the extent that time and the meeting agenda permit, any member of the public may speak to or otherwise address the Committee regarding the agenda items. *See Open Meeting and Public Participation Policy,* available at *https://www.ntia.doc.gov/category/csmac.*

Time and Date: The meeting will be held on August 15, 2017, from 8:00 a.m. to 11:00 a.m. MDT. The meeting time and the agenda topics are subject to change. The meeting will be available via two-way audio link and may be webcast. Please refer to NTIA's Web site, *https://www.ntia.doc.gov/category/csmac,* for the most up-to-date meeting agenda and access information.

Place: The meeting will be held at the Renaissance Boulder Flatiron Hotel, 500 Flatiron Boulevard, Broomfield, CO 80021. The meeting will be open to the public and members of the press on a first-come, first-served basis as space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Reed at (202) 482–5955 or *dreed@ntia.doc.gov* at least ten (10) business days before the meeting.

Status: Interested parties and members of the public are invited to attend and to submit written comments to the Committee at any time before or after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of a meeting may send them via postal mail to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4600, Washington, DC 20230. It would be helpful if paper submissions also include a compact disc (CD) that contains the comments in Microsoft Word and/or PDF file formats. CDs should be labeled with the name and organizational affiliation of the filer. Alternatively, comments may be submitted via electronic mail to *dreed@ntia.doc.gov* and should also be in one or both of the file formats specified above. Comments must be received five (5) business days before the scheduled meeting date in order to provide sufficient time for review. Comments received after this date will be distributed to the Committee, but may not be reviewed prior to the meeting.

Records: NTIA maintains records of all Committee proceedings. Committee records are available for public inspection at NTIA's Washington, DC office at the address above. Documents including the Committee's charter, member list, agendas, minutes, and reports are available on NTIA's Web site at *https://www.ntia.doc.gov/category/csmac.*

Dated: June 27, 2017.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2017–13776 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTC–C–2017–0028]

Patent and Trademark Public Advisory Committees

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice and request for nominations for the Patent and Trademark Public Advisory Committees.

SUMMARY: On November 29, 1999, the President signed into law the Patent and Trademark Office Efficiency Act (the ''Act''), Public Law 106–113, which, among other things, established two Public Advisory Committees to review the policies, goals, performance, budget and user fees of the United States Patent and Trademark Office (USPTO) with respect to patents, in the case of the Patent Public Advisory Committee, and with respect to trademarks, in the case of the Trademark Public Advisory Committee, and to advise the Director on these matters. The America Invents Act Technical Corrections Act made several amendments to the 1999 Act, including the requirement that the terms of the USPTO Public Advisory Committee members be realigned by 2014, so that December 1 be used as the start and end date, with terms staggered so that each year three existing terms expire and three new terms begin on December 1. Through this Notice, the USPTO is requesting nominations for up to three (3) members of the Patent Public Advisory Committee, and for up to three (3) members of the Trademark Public Advisory Committee, for terms of three years that begin on December 1, 2017.

DATES: Nominations must be postmarked or electronically transmitted on or before July 25, 2017.

ADDRESSES: Persons wishing to submit nominations should send the nominee's resumé by postal mail to Brendan McCommas, Acting Chief of Staff, Office of the Under Secretary of Commerce for Intellectual Property and Director of the

USPTO, Post Office Box 1450, Alexandria, Virginia 22313–1450 or by electronic mail to: *PPACnominations@uspto.gov* for the Patent Public Advisory Committee, or *TPACnominations@uspto.gov* for the Trademark Public Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Brendan McCommas, Acting Chief of Staff, Office of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, at (571) 272–8600.

SUPPLEMENTARY INFORMATION: The Advisory Committees' duties include:

- Review and advise the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on matters relating to policies, goals, performance, budget, and user fees of the USPTO relating to patents and trademarks, respectively; and
- Within 60 days after the end of each fiscal year: (1) Prepare an annual report on matters listed above; (2) transmit the report to the Secretary of Commerce, the President, and the Committees on the Judiciary of the Senate and the House of Representatives; and (3) publish the report in the Official Gazette of the USPTO.

Advisory Committees

The Public Advisory Committees are each composed of nine (9) voting members who are appointed by the Secretary of Commerce (the ''Secretary'') and serve at the pleasure of the Secretary for three-year terms. Members are eligible for reappointment for a second consecutive three-year term. The Public Advisory Committee members must be citizens of the United States and are chosen to represent the interests of diverse users of the United States Patent and Trademark Office with respect to patents, in the case of the Patent Public Advisory Committee, and with respect to trademarks, in the case of the Trademark Public Advisory Committee. Members must represent small and large entity applicants located in the United States in proportion to the number of applications filed by such applicants. The Committees must include individuals with ''substantial background and achievement in finance, management, labor relations, science, technology, and office automation.'' 35 U.S.C. 5(b)(3). Each of the Public Advisory Committees also includes three (3) non-voting members representing each labor organization recognized by the USPTO. Administration policy discourages the appointment of federally registered lobbyists to agency advisory boards and commissions (Lobbyists on Agency Boards and Commissions, *http://www.whitehouse.gov/blog/2009/09/23/lobbyist-agency-boards-and-commissions* (Sept. 23, 2009)); cf. Exec. Order No. 13490, 74 FR 4673 (January 21, 2009) (While Executive Order 13490 does not specifically apply to federally registered lobbyists appointed by agency or department heads, it sets forth the Administration's general policy of decreasing the influence of special interests in the Federal Government).

Procedures and Guidelines of the Patent and Trademark Public Advisory Committees

Each newly appointed member of the Patent and Trademark Public Advisory Committees will serve for a three-year term that begins on December 1, 2017, and ends on December 1, 2020. As required by the 1999 Act, members of the Patent and Trademark Public Advisory Committees will receive compensation for each day (including travel time) while the member is attending meetings or engaged in the business of that Advisory Committee. The enabling statute states that members are to be compensated at the daily equivalent of the annual rate of basic pay in effect for level III of the Executive Schedule under section 5314 of Title 5, United States Code. Committee members are compensated on an hourly basis, calculated at the daily rate. While away from home or regular place of business, each member shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by Section 5703 of Title 5, United States Code.

Applicability of Certain Ethics Laws

Public Advisory Committee Members are Special Government Employees within the meaning of Section 202 of Title 18, United States Code. The following additional information includes several, but not all, of the ethics rules that apply to members, and assumes that members are not engaged in Public Advisory Committee business more than 60 days during any period of 365 consecutive days.

- Each member will be required to file a confidential financial disclosure form within thirty (30) days of appointment. 5 CFR 2634.202(c), 2634.204, 2634.903, and 2634.904(b).
- Each member will be subject to many of the public integrity laws, including criminal bars against representing a party in a particular matter that came before the member's committee and that involved at least one specific party. 18 U.S.C. 205(c); *see also* 18 U.S.C. 207 for post-membership bars. A member also must not act on a matter in which the member (or any of certain closely related entities) has a financial interest. 18 U.S.C. 208.
- Representation of foreign interests may also raise issues. 35 U.S.C. 5(a)(1) and 18 U.S.C. 219.

Meetings of the Patent and Trademark Public Advisory Committees

Meetings of each Advisory Committee will take place at the call of the respective Committee Chair to consider an agenda set by that Chair. Meetings may be conducted in person, telephonically, on-line through the Internet, or by other appropriate means. The meetings of each Advisory Committee will be open to the public except each Advisory Committee may, by majority vote, meet in executive session when considering personnel, privileged, or other confidential information. Nominees must have the ability to participate in Committee business through the Internet.

Dated: June 26, 2017.

Joseph Matal,

Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2017–13769 Filed 6–29–17; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

International Design Applications (Hague Agreement)

ACTION: Proposed extension of a continuing information collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on a proposed extension of an existing collection: 0651–0075 (International Design Applications (Hague Agreement)).

DATES: Written comments must be submitted on or before August 29, 2017.

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

Email: InformationCollection@uspto.gov. Include ''0651–0075 comment'' in the subject line of the message.

Federal Rulemaking Portal: http://www.regulations.gov.

Mail: Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and

Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Rafael Bacares, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3276; or by email at *Rafael.Bacares@uspto.gov* with ''0651–0075 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

Abstract

The Patent Law Treaties Implementation Act of 2012 (PLTIA) amends the patent laws to implement the provisions of the Geneva Act of the Hague Agreement Concerning International Registration of Industrial Designs (hereinafter ''Hague Agreement'') in title 1, and the Patent Law Treaty (PLT) in title 2. The Hague Agreement is an international agreement that enables an applicant to file a single international design application which may have the effect of an application for protection for the design(s) in countries and/or intergovernmental organizations that are Parties to the Hague Agreement (the ''Contracting Parties'') designated in the application. The United States is a Contracting Party to the Hague Agreement, which took effect with respect to the United States on May 13, 2015. The Hague Agreement is administered by the International Bureau (IB) of World Intellectual Property Organization (WIPO) located in Geneva, Switzerland.

Thus, under the Hague Agreement, a U.S. applicant could file an international design application in English ''indirectly'' through the U.S. Patent and Trademark Office (''USPTO''), which will forward the application to the IB or ''directly'' with the IB. The industrial design or designs will be eligible for protection in all the Contracting Parties designated by the applicant.

The IB ascertains whether the international design application complies with formal requirements, registers the international design in the International register, and publishes the international registration in the International Designs Bulletin. The international registration contains all of the data of the international application, any reproduction of the industrial design, date of the international registration, number of the international registration, and relevant class of the International Classification.

The IB will provide a copy of the publication of the international registration to each Contracting party designated by the applicant. A designated Contracting Party may perform a substantive examination of the design application. The USPTO will perform a substantive examination for patentability of the international design application, as in the case of regular U.S. design applications.

The Hague Agreement enables applicants from a Contracting Party to obtain protection of their designs with minimal formality and expense. Additionally, under the Hague Agreement, the international registration can be centrally maintained by the IB. For example, through the IB, applicants can record changes of their representatives or changes in ownership, and renew their international registration.

II. Method of Collection

Most of the items in this collection can be submitted electronically through EFS-Web. The items can also be submitted by mail.

III. Data

Collection Name: International Design Applications (Hague Agreement).

OMB Number: 0651–0075.

IC Instruments and Forms: WIPO DM/1.

Type of Review: Extension of a Previously Reviewed Information Collection.

Affected Public: Business or other for-profits; not-for-profit institutions.

Estimated Number of Responses: 556 responses per year.

Estimated Time per Response: The USPTO estimates that the response time for activities related to International Design Applications will take the public between approximately 15 minutes (0.25 hours) to 6 hours to complete. (See Table 1.) This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO. The USPTO calculates that, on balance, it takes the same amount of time to do this, regardless of whether the public is submitting the information in paper form or electronically.

Estimated Total Response Burden Hours: 1,898.00 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $778,180. The USPTO expects that an attorney will complete these applications. The professional hourly rate for attorneys is $410. This rate is established by estimates in the 2015 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $778,180 per year.

TABLE 1—ANNUAL HOURLY COST BURDEN

IC No.	Item	Estimated time for response (hours) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Estimated annual burden (c) × (d) = (e)
1	Applicant for International Registration	6.00	156	936	$410.00	$383,750.00
2	Claim and Reproductions (Drawings)	4.00	156	624	410.00	255,840.00
3	Transmittal Letter	2.00	140	280	410.00	114,800.00
4	Appointment of a Representative	0.25 (15 minutes)	15	3.75	410.00	1,537.50
5	Petition to Excuse a Failure to Comply with a Time Limit.	4.00	1	4	410.00	1,640.00
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16.	4.00	1	4	410.00	1,640.00
7	Petition to Review a Filing Date	4.00	2	8	410.00	3,280.00
8	Fee Authorization	0.25 (15 minutes)	31	7.75	410.00	3,177.50
9	Petitions to the Commissioner	4.00	1	4	410.00	1,640.00

TABLE 1—ANNUAL HOURLY COST BURDEN—Continued

IC No.	Item	Estimated time for response (hours) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Estimated annual burden (c) × (d) = (e)
10	Transmittal of Issue Fee to UPSTO for an International Design Application.	0.50 (30 minutes)	1	0.50	410.00	205.00
11	Declaration on Inventorship for Purposes of Designation of the United States.	0.50 (30 minutes)	46	23	410.00	9,430.00
12	Substitute Statement in Lieu of a Declaration of Inventorship for the Purposes of Designating the United States.	0.50 (30 minutes)	1	0.50	410.00	205.00
13	Assignment Cover Sheet	0.50 (30 minutes)	5	0.50	410.00	1,025.00
Totals			556	1,898.00		778,180.00

Estimated Total Annual (Non-hour) Respondent Cost Burden: $424,245.90.

There are no maintenance, operation, capital start-up, or recordkeeping costs associated with this collection. However, this collection does have annual (non-hour) costs in the form of postage costs and filing fees.

Although the USPTO prefers that the items in this collection be submitted electronically, the items may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average cost for a paper submission will be $5.95 and that 62 submissions will be mailed to the USPTO per year.

TABLE 2—POSTAGE COSTS

IC No.	Item	Estimated annual responses (a)	Postage costs (b)	Estimated total postage costs (c) (a) × (b)
1	Applicant for International Registration	1	$5.95	$5.95
2	Claim and Reproductions (Drawings)	1	5.95	5.95
3	Transmittal Letter	1	5.95	5.95
4	Appointment of a Representative	1	5.95	5.95
5	Petition to Excuse a Failure to Comply with a Time Limit	1	5.95	5.95
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16.	1	5.95	5.95
7	Petition to Review a Filing Date	1	5.95	5.95
8	Fee Authorization	1	5.95	5.95
9	Petitions to the Commissioner	1	5.95	5.95
10	Transmittal of Issue Fee to USPTO for an International Design Application.	1	5.95	5.95
11	Declaration on Inventorship for Purposes of Designation of the United States.	46	5.95	273.70
12	Substitute Statement in Lieu of a Declaration of Inventorship for the Purposes of Designating the United States.	1	5.95	5.95
13	Assignment Cover Sheet	5	5.95	29.75
Total Postage Costs	62		368.90	

This collection also contains an annual (non-hour) cost burden in the way of filing fees. The total estimated filing costs for this collection is $423,876 detailed in Table 3 below.

TABLE 3—FILING FEES

IC No.	Item	Estimated annual response (a)	Filing fee amount (b)	Total filing fee cost (c) (a) × (b)
1	Application for International Registration (electronic)—Average Fee per registration to WIPO (collecting for WIPO).	155	$1,766.00	$273,730.00

TABLE 3—FILING FEES—Continued

IC No.	Item	Estimated annual response (a)	Filing fee amount (b)	Total filing fee cost (c) (a) × (b)
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (large entity).	155	760.00	117,800.00
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (small entity).	1	380.00	380.00
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (micro entity).	1	190.00	190.00
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (large entity).	155	120.00	18,600.00
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (small entity).	1	120.00	120.00
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (micro entity).	1	120.00	120.00
1	Application for International Registration (non-electronic)—Average Fee per registration to WIPO (collecting for WIPO).	1	1,766.00	1,766.00
1	Application for International Registration (non-electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (large entity).	1	760.00	760.00
1	Application for International Registration (non-electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (small entity).	1	380.00	380.00
1	Application for International Registration (non-electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (micro entity).	1	190.00	190.00
1	Application for International Registration (non-electronic)—Transmittal Fee (set by and collected by USPTO) (large entity).	1	120.00	120.00
1	Application for International Registration (non-electronic)—Transmittal Fee (set by and collected by USPTO) (small entity).	1	120.00	120.00
1	Application for International Registration (non-electronic)—Transmittal Fee (set by and collected by USPTO) (micro entity).	1	120.00	120.00
5	Petition to Excuse a Failure to Comply with a Time Limit (electronic) (large entity).	1	1,700.00	1,700.00
5	Petition to Excuse a Failure to Comply with a Time Limit (electronic) (small entity).	1	850.00	850.00
5	Petition to Excuse a Failure to Comply with a Time Limit (electronic) (micro entity).	1	850.00	850.00
5	Petition to Excuse a Failure to Comply with a Time Limit (non-electronic) (large entity).	1	1,700.00	1,700.00
5	Petition to Excuse a Failure to Comply with a Time Limit (non-electronic) (small entity).	1	850.00	850.00
5	Petition to Excuse a Failure to Comply with a Time Limit (non-electronic) (micro entity).	1	850.00	850.00
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (electronic).	1	180.00	180.00
7	Petition to Review a Filing Date (electronic) (large entity)	2	400.00	400.00
7	Petition to Review a Filing Date (electronic) (small entity)	1	200.00	200.00
7	Petition to Review a Filing Date (electronic) (micro entity)	1	100.00	100.00
7	Petition to Review a Filing Date (non-electronic) (large entity)	1	400.00	400.00
7	Petition to Review a Filing Date (non-electronic) (small entity)	1	200.00	200.00
7	Petition to Review a Filing Date (non-electronic) (micro entity)	1	100.00	100.00
9	Petitions to Commissioner (electronic) (large entity)	1	400.00	400.00
9	Petitions to Commissioner (electronic) (small entity)	1	200.00	200.00
9	Petitions to Commissioner (electronic) (micro entity)	1	100.00	100.00
	Totals	493		423,876.00

The USPTO estimates that the total annual (non-hour) respondent cost burden for this collection in the forms of postage costs and filing fees is estimated to be approximately be $424,245.90 per year ($368.90 in postage costs and $423,876 in filing fees).

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the USPTO's request for OMB approval. All comments will become a matter of public record.

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated

collection techniques or other forms of information technology.

Marcie Lovett,

Records and Information Governance Division Director, USPTO, Office of the Chief Technology Officer.

[FR Doc. 2017–13716 Filed 6–29–17; 8:45 am]

BILLING CODE P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletion from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes a service previously furnished by such agency.

Comments Must Be Received on or Before: 7/30/2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed.

Products

NSN(s)—Product Name(s):

9930–00–NIB–0105—Kit, Post Mortem Bag, Basic, Straight Zipper, 36″ × 90″

9930–00–NIB–0106—Kit, Post Mortem Bag, Basic, Curved Zipper, 36″ × 90″

9930–00–NIB–0107—Kit, Post Mortem Bag, Heavy Duty, 36″ × 90″

9930–00–NIB–0108—Kit, Post Mortem Bag, Heavy Duty, XL, 72″ × 90″

9930–00–NIB–0109—Kit, Disaster Bag with ID Tags, 34″ × 96″

Mandatory for: Broad Government Requirement

Mandatory Source(s) of Supply: BOSMA Enterprises, Indianapolis, IN

Contracting Activity: Defense Logistics Agency Troop Support

Distribution: B-List

Services

Service Type: Custodial Service

Mandatory for: Defense Intelligence Agency, Defense Intelligence Agency Headquarters, Building 6000, 200 MacDill Blvd., Joint Base Anacostia-Bolling, Washington, DC

Defense Intelligence Agency, Missile and Space Intelligence Center/EOE Complex, Bldgs. 4545 Fowler Rd. & 7533 Mathews Rd., Redstone Arsenal, AL

Mandatory Source(s) of Supply: CW Resources, Inc., New Britain, CT

Contracting Activity: Dept of Defense, Virginia Contracting Agency, DIAC CF02E

Service Type: Janitorial Service

Mandatory for: U.S. Census Bureau, National Processing Center, 1201 E 10th Street, Jeffersonville, IN

Mandatory Source(s) of Supply: Rauch, Inc., New Albany, IN

Contracting Activity: Dept of Commerce/Bureau of the Census

Service Type: Base Supply Center Service

Mandatory for: U.S. Air Force, Robins Air Force Base, 375 Perry Street, Suite A, Robins AFB, GA

Mandatory Source(s) of Supply: Alabama Industries for the Blind, Talladega, AL

Contracting Activity: Dept. of the Air Force, FA8501 AFSC PZIO

Deletion

The following service is proposed for deletion from the Procurement List:

Service

Service Type: Janitorial/Custodial Service

Mandatory for: U.S. Army Reserve Center: 10541 Calle Lee, Building 2, Los Alamitos, CA

Mandatory Source(s) of Supply: Elwyn, Aston, PA

Contracting Activity: Dept of the Army, W6QM MICC–MOFFETT FIELD

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2017–13832 Filed 6–29–17; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES Effective Date: 7/30/2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION

Additions

On 5/26/2017 (82 FR 24308–24309), 6/2/2017 (82FR 25602), and 6/16/2017 (82 FR 27698), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN(s)—Product Name(s):
MR 10760—Activity Pack, Licensed, Pokemon, Includes Shipper 20760
MR 10761—Sticker Pack, Licensed, Pokemon, Includes Shipper 20760
MR 10762—Pen, Licensed, Pokemon, Includes Shipper 20762
MR 10763—Kid's Baking Tools, Licensed, Whisk and Spoon, Includes Shipper 20763
MR 10764—Kid's Baking Tools, Licensed, Turner and Spatula, Includes Shipper 20763
MR 10765—Kid's Baking Tools, Licensed, Rolling Pin and Cookie Cutters, Includes Shipper 20763
MR 10766—Kid's Baking Tools, Licensed, Decorating Set, Includes Shipper 20763
Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
NSN(s)—Product Name(s):
MR 1176—Mop, Sticky
MR 1177—Refill, Mop, Sticky
Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC
NSN(s)—Product Name(s): MR 804—Grill Basket
Mandatory Source(s) of Supply: Cincinnati Association for the Blind, Cincinnati, OH

The following information is applicable to all products listed above.

Mandatory for: The requirements of military commissaries and exchanges in accordance with the Code of Federal Regulations 41 CFR 51–6.4.
Contracting Activity: Defense Commissary Agency
Distribution: C-List

Services

Service Type: Individual Equipment Elements (IEE) Store
Mandatory for: U.S. Air Force, Elmendorf AFB, 10480 Sijan Avenue, Joint Base Elmendorf-Richardson, AK
Mandatory Source(s) of Supply: RLCB, Inc., Raleigh, NC
Contracting Activity: DEPT OF THE AIR FORCE, FA5000 673 CONS LGC
Service Type: Dispenser Machine Support Service
Mandatory for: U.S. Navy, Naval Medical Center San Diego, 34800 Bob Wilson Drive, San Diego, CA
Mandatory Source(s) of Supply: Job Options, Inc., San Diego, CA
Contracting Activity: DEPT OF THE NAVY, NAVAL MEDICAL CENTER
Service Type: Grounds Maintenance
Mandatory for: U.S. Coast Guard, U.S. Coast Guard Base Los Angeles/Long Beach, 1001 S. Seaside Avenue, San Pedro, CA
Mandatory Source(s) of Supply: Goodwill Industries of Southern California, Panarama City, CA
Contracting Activity: U.S. COAST GUARD, SILC BSS (00084)

Deletions

On 5/19/2017 (82 FR 22972) and 5/26/2017 (82 FR 24308–24309), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and/or service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN(s)—Product Name(s): 5340–00–NSH–0008—Loop, Kevlar
5340–00–NSH–0009—Link, Quick Release
Mandatory Source(s) of Supply: Community Option Resource Enterprises, Inc. (COR Enterprises), Billings, MT
Contracting Activity: NAVSUP WEAPON SYSTEMS SUPPORT
NSN(s)—Product Name(s): MR 508—Candle, Spring Scents
Mandatory Source(s) of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: Defense Commissary Agency
NSN(s)—Product Name(s): 8410–01–069–6611—Shirt, Dress, Navy, Women's, Short Sleeved, White, 32 × 13
Mandatory Source(s) of Supply: Middle Georgia Diversified Industries, Inc., Dublin, GA
Contracting Activity: Defense Logistics Agency Troop Support
NSN(s)—Product Name(s):
8415–01–390–8537—Coat, Combat Type VI, Army, Woodland Camouflage, XS/XS
8415–01–390–8538—Coat, Combat Type VI, Army, Woodland Camouflage, XS/R
8415–01–390–8539—Coat, Combat Type VI, Army, Woodland Camouflage, Small/Short
8415–01–390–8540—Coat, Combat Type VI, Army, Woodland Camouflage, Small/X Long
8415–01–390–8541—Coat, Combat Type VI, Army, Woodland Camouflage, Medium/X Short
8415–01–390–8542—Coat, Combat Type VI, Army, Woodland Camouflage, Medium/XX Short
8415–01–390–8543—Coat, Combat Type VI, Army, Woodland Camouflage, Small/Long
8415–01–390–8544—Coat, Combat Type VI, Army, Woodland Camouflage, Medium Regular
8415–01–390–8545—Coat, Combat Type VI, Army, Woodland Camouflage, Small/Regular
8415–01–390–8546—Coat, Combat Type VI, Army, Woodland Camouflage, X Small/Short
8415–01–390–8547—Coat, Combat Type VI, Army, Woodland Camouflage, Medium/X Long
8415–01–390–8548—Coat, Combat Type VI, Army, Woodland Camouflage, Medium/Short
8415–01–390–8549—Coat, Combat Type VI, Army, Woodland Camouflage, Medium/Long
8415–01–390–8550—Coat, Combat Type VI, Army, Woodland Camouflage, Large/Regular
8415–01–390–8551—Coat, Combat Type VI, Army, Woodland Camouflage, Large/X Long
8415–01–390–8552—Coat, Combat Type VI, Army, Woodland Camouflage, X Large/Long
8415–01–390–8553—Coat, Combat Type VI, Army, Woodland Camouflage, Large/Long
8415–01–390–8555—Coat, Combat Type VI, Army, Woodland Camouflage, XLR
8415–01–390–8557—Coat, Combat Type VI, Army, Woodland Camouflage, LXS
8415–01–390–9641—Coat, Combat Type VI, Army, Woodland Camouflage, XSS
8415–01–390–9646—Coat, Combat Type VI, Army, Woodland Camouflage, XSXS
8415–01–390–9648—Coat, Combat Type VI, Army, Woodland Camouflage, LS
Mandatory Source(s) of Supply: UNKNOWN
Contracting Activity: Defense Logistics Agency Troop Support
NSN(s)—Product Name(s): 2320–01–398–7190—Combat Identification Kit, HMMWV TOW Platform, Brown
Mandatory Source(s) of Supply: Crossroads Rehabilitation Center, Inc., Indianapolis, IN
Contracting Activity: W4GG HQ US ARMY TACOM
NSN(s)—Product Name(s): 8415–00–NSH–0503—Shirt, Underwear, Collared,

Chemical Protection, MPS, Army, 56
Mandatory Source(s) of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: W40M NORTHERN REGION CONTRACT OFC

Services

Service Type: Custodial Service
Mandatory for: GSA, Parking Lot: 12th & C Streets, SW., Washington, DC
Mandatory Source(s) of Supply: Anchor Mental Health Association, Washington, DC
Contracting Activity: PUBLIC BUILDINGS SERVICE, WPHBD—WEST REPAIR & ALTERATIONS CONTRACTS BRANCH
Service Type: Janitorial/Custodial Services
Mandatory for: GSA Federal Supply Service Depot: 4100 West 76th Street, Chicago, IL
Mandatory Source(s) of Supply: Lester and Rosalie Anixter Center, Chicago, IL
Contracting Activity: General Services Administration, FPDS Agency Coordinator
Service Type: Switchboard Operation Service
Mandatory for: Eglin Air Force Base: East of Memorial Trail (excluding the airfield), Eglin, FL
Mandatory Source(s) of Supply: Lakeview Center, Inc., Pensacola, FL
Contracting Activity: Dept of the Air Force, FA2823 AFTC PZIO

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2017–13834 Filed 6–29–17; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Calendar Year 2018 TRICARE Young Adult Program Premium Update

AGENCY: Office of the Secretary of Defense, Department of Defense.

ACTION: Notice of updated TRICARE Young Adult Premiums for Calendar Year 2018.

SUMMARY: This notice provides the updated TRICARE Young Adult program premiums for Calendar Year (CY) 2018.

DATES: The CY 2018 rates contained in this notice are effective for services on or after January 1, 2018.

ADDRESSES: Defense Health Agency, TRICARE Health Plan, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042–5101.

FOR FURTHER INFORMATION CONTACT: Mr. Mark A. Ellis, (703) 681–0039.

SUPPLEMENTARY INFORMATION: The final rule published in the **Federal Register** (FR) on May 29, 2013 (78 FR 32116–32121) sets forth rules to implement the TRICARE Young Adult (TYA) program as required by Title 10, United States Code, Section 1110b. Included in the final rule were provisions for updating the TYA premiums for each CY. By law, qualified young adult dependents are charged TYA premiums that represent the full government cost of providing such coverage.

The Defense Health Agency has updated the monthly premiums for CY 2018 as shown below:

MONTHLY TYA PREMIUMS FOR CY 2018

Type of coverage	Monthly rate
TRICARE Select Plans	$225
TRICARE Prime Plans	324

The above premiums are effective for services rendered on or after January 1, 2018.

Dated: June 26, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–13725 Filed 6–29–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Defense Science Board (DSB) 2017 Summer Study Task Force on Countering Anti-access Systems with Longer Range and Standoff Capabilities (''the Long Range Effects 2017 Summer Study Task Force'') will meet in closed session on Thursday, July 13, 2017 from 7:55 a.m. to 4:00 p.m. and Friday, July 14, 2017 from 8:00 a.m. to 4:00 p.m. at Strategic Analysis Inc., The Executive Conference Center, 4075 Wilson Boulevard, 3rd Floor, Arlington, VA 22203.

DATES: Thursday, July 13, 2017 from 7:55 a.m. to 4:00 p.m. and Friday, July 14, 2017 from 8:00 a.m. to 4:00 p.m.

ADDRESSES: Strategic Analysis Inc., The Executive Conference Center, 4075 Wilson Boulevard, 3rd Floor, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Defense Science Board Designated Federal Officer (DFO) Ms. Karen D.H. Saunders, (703) 571–0079 (Voice), (703) 697–1860 (Facsimile), *karen.d.saunders.civ@mail.mil* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140. Web site: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the Web site.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Defense Science Board was unable to provide public notification concerning its meeting on July 13 through 14, 2017, of the Defense Science Board 2017 Summer Study Task Force on Countering Anti-access Systems with Longer Range and Standoff Capabilities, as required by 41 CFR 102–3.150(a). Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) 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.

The mission of the DSB is to provide independent advice and recommendations on matters relating to the Department of Defense's (DoD) scientific and technical enterprise. The objective of the Long Range Effects 2017 Summer Study Task Force is to explore new defense systems and technologies that will enable cost effective power projection that relies on the use of longer stand-off distances than current capabilities. System components may be deployed on manned or unmanned platforms with a range of potential autonomous capabilities. Use of cost reducing technology and advanced production practices from defense and commercial industry may be a major part of the strategy for deploying adequate numbers of weapons. This two-day session will focus on coalescing all the information from briefings presented during the January, February, March, April, and May meetings of the Long Range Effects 2017 Summer Study Task Force. The four panels (Architecture; Intelligence, Surveillance, and Reconnaissance; Basing, Delivery, and Weapons; and Command, Control, Communications, and Cyber) will meet simultaneously to discuss topics and analyze data in support of the study. Day Two will close with discussion of the four panels' work.

In accordance with section 10(d) of the FACA and 41 CFR 102–3.155, the DoD has determined that the Long Range Effects 2017 Summer Study Task

Force meeting will be closed to the public. Specifically, the Under Secretary of Defense (Acquisition, Technology, and Logistics), in consultation with the DoD Office of General Counsel, has determined in writing that the meeting will be closed to the public because matters covered by 5 U.S.C. 552b(c)(1) will be considered. The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the Under Secretary of Defense for Acquisition, Technology, and Logistics.

In accordance with section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the Long Range Effects 2017 Summer Study Task Force members at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB's DFO—Ms. Karen D.H. Saunders, Executive Director, Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301, via email at *karen.d.saunders.civ@mail.mil* or via phone at (703) 571–0079 at any point; however, if a written statement is not received at least 3 calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the Long Range Effects 2017 Summer Study Task Force until the next meeting of this task force. The DFO will review all submissions with the Long Range Effects 2017 Summer Study Task Force Co-Chairs and ensure they are provided to Long Range Effects 2017 Summer Study Task Force members prior to the end of the two day meeting on July 14, 2017.

Dated: June 26, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–13691 Filed 6–29–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Meetings for the Draft Environmental Impact Statement/ Overseas Environmental Impact Statement for Navy Atlantic Fleet Training and Testing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969 and regulations implemented by the Council on Environmental Quality, the Department of the Navy (DoN) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement (EIS)/Overseas EIS (OEIS) for public release on June 30, 2017, to evaluate the potential environmental effects from training and testing activities conducted within the Navy's Atlantic Fleet Training and Testing (AFTT) Study Area.

The Study Area is in the western Atlantic Ocean and encompasses the waters along the east coast of North America, the Gulf of Mexico, portions of the Caribbean Sea, Navy pierside locations and port transit channels, waters near civilian ports, and inland waters (*e.g.,* lower Chesapeake Bay). The Study Area covers approximately 2.6 million square nautical miles of ocean area and includes designated Navy operating areas and special use airspace.

The National Marine Fisheries Service (NMFS) is a Cooperating Agency for the EIS/OEIS.

With the filing of the Draft EIS/OEIS, the DoN is initiating a 60-day public comment period and has scheduled five public meetings to receive oral and written comments on the Draft EIS/OEIS. This notice announces the dates and locations of the public meetings for this Draft EIS/OEIS and provides supplementary information about the environmental planning effort.

Dates and Addresses: The Draft EIS/OEIS public review period will begin June 30, 2017, and end on August 29, 2017. The Navy will hold five public meetings to inform the public about the Proposed Action and the alternatives under consideration, and to provide an opportunity for the public to comment on the Proposed Action, alternatives, and the adequacy and accuracy of the analysis in the Draft EIS/OEIS. Each of the public meetings will be conducted in an open-house format with informational stations staffed by DoN representatives. These representatives will be available during the public meeting to clarify information related to the Draft EIS/OEIS. Federal, state, and local agencies and officials, and interested groups and individuals are encouraged to provide comments in person at any of the public meetings or in writing during the public comment period.

The public meetings will be held between 4 p.m. and 8 p.m. on the following dates and at the following locations:

1. Wednesday, July 19, 2017, Hotel Providence, 139 Mathewson Street, Providence, RI 02903.

2. Tuesday, July 25, 2017, UNC Institute of Marine Sciences, 3431 Arendell Street, Morehead City, NC 28557.

3. Wednesday, July 26, 2017, Nauticus, 1 Waterside Drive, Norfolk, VA 23510.

4. Tuesday, August 1, 2017, Prime F. Osborn III Convention Center, 1000 Water Street, Jacksonville, FL 32204.

5. Thursday, August 3, 2017, Gulf Coast State College Conference Center, 5230 W. Highway 98, Panama City, FL 32401.

Attendees will be able to submit comments in writing or orally using a voice recorder at the public meetings. Equal weight will be given to oral and written statements. Comments may also be submitted by U.S. postal mail or electronically via the project Web site provided below. Written comments may be submitted by mail to Naval Facilities Engineering Command Atlantic, Attn: Code EV22KP (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278 and through the project Web site; all written comments must be post marked or received by August 29, 2017. All statements, oral or written, submitted during the public review period will become part of the public record on the Draft EIS/OEIS and will be considered in preparation of the Final EIS/OEIS.

Public meeting details will also be announced in local newspapers and on the project Web site: *www.AFTTEIS.com.*

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command Atlantic, Attn: Code EV22KP (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278.

SUPPLEMENTARY INFORMATION: A Notice of Intent (NOI) to prepare this DEIS/OEIS was published in the **Federal Register** on November 12, 2015, (Vol. 80, No. 218, p. 69951). A correction to the Notice of Intent was issued on December 1, 2015 and published in the **Federal Register** (Vol. 80, No. 230, p.

75076) to update the deadline for comment submission.

The DoN's Proposed Action is to conduct military readiness training activities, and research, development, testing, and evaluation activities in the AFTT Study Area. These military readiness activities include the use of active sonar and explosives within existing range complexes and testing ranges and additional areas located in the Atlantic Ocean along the eastern coast of North America, in portions of the Caribbean Sea, the Gulf of Mexico, at Navy pierside locations and port transit channels, near civilian ports, and in bays, harbors, and inland waterways (*e.g.,* the lower Chesapeake Bay). These military readiness activities are generally consistent with those analyzed in the AFTT EIS/OEIS completed in December 2013 and are representative of training and testing that the Navy has been conducting in the AFTT Study Area for decades.

Potential direct, indirect, cumulative, short-term, long-term, irreversible, and irretrievable impacts to the environment from two action alternatives and a No Action Alternative are evaluated in the Draft EIS/OEIS. Resources evaluated include air quality, sediments and water quality, vegetation, invertebrates, marine habitats, fish, marine mammals, sea turtles and other marine reptiles, birds and bats, cultural resources, socioeconomic resources, and public health and safety.

Based on the results of the analysis, the Navy has requested from NMFS a Letter of Authorization (LOA) in accordance with the MMPA to authorize the incidental take of marine mammals that may result from the implementation of the activities analyzed in the AFTT Draft EIS/OEIS. In accordance with Section 7 of the Endangered Species Act, the Navy is consulting with NMFS and U.S. Fish and Wildlife Service (USFWS) for potential impacts to federally listed species. The Navy will complete all required consultations and comply with other applicable laws and regulations.

The Draft EIS/OEIS addresses mitigation measures designed to help reduce or avoid potential impacts to marine resources, including new mitigation measures that include expanded geographic mitigation areas, and updates to procedural mitigation measures. In addition, the Draft EIS/OEIS addresses marine species monitoring efforts designed to track compliance with authorizations and to investigate the effectiveness of mitigation measures implemented as part of the Proposed Action. The proposed mitigation measures, including new mitigation measures, would be implemented under either alternative in order to maximize the mitigation benefits to the environment.

Mitigation measures are being coordinated through the consultation and permitting processes. The DoN will also consider public comments on proposed mitigation measures described in this Draft EIS/OEIS.

Notice of the availability of the draft EIS/OEIS was distributed to federal, state, and local agencies, elected officials, and other interested individuals and organizations. Copies of the Draft EIS/OEIS are available for public review at the following libraries:

1. Anne Arundel County Public Library, 5 Harry S. Truman Parkway, Annapolis, MD 21401.
2. Bay County Public Library, 898 West 11th Street, Panama City, FL 32401.
3. Ben May Main Library, 701 Government Street, Mobile, AL 36602.
4. Boston Public Library, Central Library, 700 Boylston Street, Boston, MA 02116.
5. Camden County Public Library, 1410 Highway 40 E, Kingsland, GA 31548.
6. Carteret County Public Library, 1702 Live Oak Street, Suite 100, Beaufort, NC 28516.
7. Charleston County Public Library, Main Library, 68 Calhoun Street, Charleston, SC 29401.
8. Corpus Christi Public Library, La Retama Central Library, 805 Comanche, Corpus Christi, TX 78401.
9. East Bank Regional Library, 4747 West Napoleon Avenue, Metairie, LA 70001.
10. Dare County Library, Manteo, 700 Highway 64/264, Manteo, NC 27954.
11. Havelock-Craven County Public Library, 301 Cunningham Boulevard, Havelock, NC 28532.
12. Jacksonville Public Library, 303 North Laura Street, Jacksonville, FL 32202.
13. Dare County Library, Kill Devil Hills, 400 Mustian Street, Kill Devil Hills, NC 27948.
14. Houston Public Library, 500 McKinney Street, Houston, TX 77002.
15. New Hanover County Public Library, 201 Chestnut Street, Wilmington, NC 28401.
16. New Orleans Public Library, Main Library, 219 Loyola Avenue, New Orleans, LA 70112.
17. Onslow County Public Library, 58 Doris Avenue East, Jacksonville, NC 28540.
18. Pascagoula Public Library, 3214 Pascagoula Street, Pascagoula, MS 39567.
19. West Florida Public Library, Pensacola Library, 239 North Spring Street, Pensacola, FL 32502.
20. Portland Public Library, 5 Monument Square, Portland, ME 04101.
21. Providence Public Library, 150 Empire Street, Providence, RI 02903.
22. Public Library of New London, 63 Huntington Street, New London, CT 06320.
23. Slover Memorial Main Library, 235 East Plume Street, Norfolk, VA 23510.
24. Walton County Library, Coastal Branch Library, 437 Greenway Trail, Santa Rosa Beach, FL 32459.
25. Webb Memorial Library and Civic Center, 812 Evans Street, Morehead City, NC 28557.
26. West Florida Public Library, Southwest Branch, 12248 Gulf Beach Highway, Pensacola, FL 32507.
27. Mandel Public Library of West Palm Beach, 411 Clematis Street, West Palm Beach, FL 33401.

Copies of the AFTT Draft EIS/OEIS are available for electronic viewing at *www.AFTTEIS.com.* A paper copy of the Executive Summary and a single compact disc (CD) of the Draft EIS/OEIS will be made available upon written request by contacting: Naval Facilities Engineering Command Atlantic, Attn: Code EV22KP (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278.

Authority: 42 U.S.C. 4332, E.O. 12114, and 40 CFR 1500–1508.

Dated: June 27, 2017.

A.M. Nichols,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2017–13790 Filed 6–29–17; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2017–FSA–0047]

Privacy Act of 1974; Matching Program

AGENCY: Department of Education.

ACTION: Notice of the re-establishment of a computer matching program.

SUMMARY: This document provides notice of the re-establishment of a computer matching program between the Department of Education (ED) and the Defense Manpower Data Center (DMDC) of the U.S. Department of Defense (DoD).

DATES: We must receive your comments on or before July 31, 2017.

The re-established matching program will be effective on the latest of the following three dates: (A) August 1,

2017; (B) 30 days from June 30, 2017, as required by 5 U.S.C. 552a(e)(12) and OMB Circular A–108, assuming that ED receives no public comments or receives public comments but makes no changes to this notice as a result of the public comments, or 30 days from the date on which ED publishes a subsequent matching program notice in the **Federal Register**, assuming that ED receives public comments and revises this notice as a result of public comments; or (C) 60 days from the date on which ED transmits the report of the matching program, as required by 5 U.S.C. 552a(r) and OMB Circular A–108, to OMB, the U.S. House Committee on Oversight and Government Reform, and the U.S. Senate Committee on Homeland Security and Governmental Affairs, unless OMB waives any days of the 60-day review period for compelling reasons, in which case 60 days minus the number of days waived by OMB from the date of ED's transmittal of the report of the matching program.

The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months thereafter, if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''help'' tab.
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments, address them to Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE., Washington, DC 20002–5345.

Privacy Note: ED's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Ms. Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE., Washington, DC 20002–5345. Telephone: (202) 377–3385.

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

SUPPLEMENTARY INFORMATION: We provide this notice in accordance with 5 U.S.C. 552a (commonly known as the Privacy Act of 1974, as amended); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–108, 81 FR 94424 (December 23, 2016), *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a108/omb_circular_a-108.pdf.*

Under sections 420R and 473(b) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070h and 20 U.S.C. 1087mm(b)), the Secretary of Defense must provide the Secretary of Education with information to identify the children of military personnel who have died as a result of their military service in Iraq or Afghanistan after September 11, 2001, to determine if the child is eligible for increased amounts of title IV, HEA program assistance. DoD and ED have determined that matching data contained in the DoD DMDC system and the Defense Enrollment Eligibility Reporting System (DEERS) against ED's Federal Student Aid Application File (18–11–01) is the only practical method that the agencies can use to meet the statutory requirements of the HEA.

The prior Computer Matching Agreement (CMA) was published in the **Federal Register** on January 2, 2015 (80 FR 37). Under the provisions of the Computer Matching and Privacy Protection Act of 1988, Public Law 100–503, the CMA was renewed for an additional 12 months through July 31, 2017 because: (1) The program was conducted without change; and (2) each Data Integrity Board Chairperson certified in writing that the program was conducted in compliance with the CMA. ED and DoD are now re-establishing the CMA through this notice.

PARTICIPATING AGENCIES:

ED and DoD

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

Sections 420R and 473(b) of the HEA (20 U.S.C. 1070h and 20 U.S.C. 1087mm(b)) and 5 U.S.C. 552a.

PURPOSES:

This matching program identifies children whose parent or guardian was a member of the Armed Forces of the United States and died as a result of performing military service in Iraq or Afghanistan after September 11, 2001. These children (referred to as qualifying students) may be eligible for a greater amount of title IV, HEA program assistance. A qualifying student must have been age 24 or younger at the time of the parent's or guardian's death, or, if older than 24, enrolled part-time or full-time in an institution of higher education at the time of the parent's or guardian's death. Beginning July 1, 2010, students who are otherwise qualified children of deceased U.S. military who meet the requirements of section 420R of the HEA (20 U.S.C. 1070h) may also be eligible for higher amounts of title IV, HEA program assistance.

CATEGORIES OF INDIVIDUALS:

The individuals whose records are included in this matching program are dependents of service personnel who died as a result of performing their military service in Iraq or Afghanistan after September 11, 2001, which records are located in the DoD DMDC and DEERS systems, and all students who complete a Free Application for Federal Student Aid.

CATEGORIES OF RECORDS:

DoD data include the individual's first and last name, Social Security number (SSN), date of birth, and the parent's or guardian's date of death for each qualifying dependent record. ED uses the SSN, date of birth, and the first two letters of an applicant's last name to match with the Federal Student Aid Application File.

SYSTEM(S) OF RECORDS:

ED system of records: Federal Student Aid Application File (18–11–01) (76 FR 46774). DoD system of records: DMDC 01, Defense Manpower Data Center Data Base (76 FR 72391) (November 23, 2011), and DMDC 02 DoD Defense Enrollment Eligibility Reporting Systems (DEERS) (81 FR 49210) (July 27, 2016).

Accessible Format: Individuals with disabilities can obtain this document in

an accessible format (such as, braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available through the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: June 27, 2017.

Matthew Sessa,

Acting Chief Operating Officer Federal Student Aid.

[FR Doc. 2017–13772 Filed 6–29–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, July 20, 2017, 6:00 p.m.

ADDRESSES: Barkley Centre, 111 Memorial Drive, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6825.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management and related activities.

Tentative Agenda

- Call to Order, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Breaks Taken As Appropriate

Public Participation: The EM SSAB, Paducah, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Woodard as soon as possible in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jennifer Woodard at the telephone number listed above. Requests must be received as soon as possible prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above.

Minutes: Minutes will be available by writing or calling Jennifer Woodard at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.pgdpcab.energy.gov/2017_meetings.htm.*

Issued at Washington, DC, on June 26, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–13806 Filed 6–29–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register.**

DATES:

Monday, July 24, 2017 1:00 p.m.–4:30 p.m.

Tuesday, July 25, 2017 9:00 a.m.–4:45 p.m.

ADDRESSES: Applied Research Center, 301 Gateway Drive, Aiken, SC 29803.

FOR FURTHER INFORMATION CONTACT: Susan Clizbe, Office of External Affairs, Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–8281.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Monday, July 24, 2017

Opening, Minutes Approval, Chair Update, and Agenda Review Agency Updates
Break
Administrative & Outreach Committee Update
Facilities Disposition & Site Remediation Committee Update
Nuclear Materials Committee Update
Strategic & Legacy Management Committee Update
Waste Management Committee Update
Draft Recommendations Discussion
Public Comments
Recess

Tuesday, July 25, 2017

Reconvene
Agenda Review
Presentations:
- Plutonium Program Overview/ Update
- Atoms for Peace Overview
- Salt Waste Processing Facility Status and Liquid Waste Integration

Lunch Break
Presentations:
- Wounded Warrior Program
- Federal Oversight of Cleanup

- Community Reuse Organization
- Recruitment and Retention

Break
Public Comments
Recommendations Voting
Adjourn

Public Participation: The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Susan Clizbe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Susan Clizbe's office at the address or telephone listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Susan Clizbe at the address or phone number listed above. Minutes will also be available at the following Web site: *http://cab.srs.gov/srs-cab.html.*

Issued at Washington, DC, on June 26, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–13807 Filed 6–29–17; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9959–95–OA]

Notice of Meeting of the EPA Children's Health Protection Advisory Committee (CHPAC)

AGENCY: Environmental Protection Agency.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the next meeting of the Children's Health Protection Advisory Committee (CHPAC) will be held July 18 and 19 at the Holiday Inn Capitol, 550 C Street SW., Washington, DC 20024. The CHPAC advises the Environmental Protection Agency on science, regulations, and other issues relating to children's environmental health.

DATES: July 18 and 19 at Holiday Inn Capitol in Washington, DC.

ADDRESSES: 550 C Street SW., Washington, DC, 20024.

FOR FURTHER INFORMATION CONTACT: Martha Berger, Office of Children's Health Protection, USEPA, MC 1107T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 564–2191 or berger. *martha@epa.gov*.

SUPPLEMENTARY INFORMATION: The meetings of the CHPAC are open to the public. An agenda will be posted to *epa.gov/children*.

Access and Accommodations: For information on access or services for individuals with disabilities, please contact Martha Berger at 202–564–2191.

Dated: March 1, 2017.

Martha Berger,

Designated Federal Official.

[FR Doc. 2017–13656 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9033–9]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)
Filed 06/19/2017 Through 06/23/2017
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170111, Final, DOC, PROG, Non-Contiguous Region of the Nationwide Public Safety Broadband Network, Review Period Ends: 07/31/2017, Contact: Amanda Goebel Pereira 202–280–9364.

EIS No. 20170112, Draft Supplement, USACE, AK, Alaska Stand Alone Pipeline Project, Comment Period Ends: 08/14/2017, Contact: Sandy P. Gibson 907–753–2877.

EIS No. 20170113, Final, FERC, WV, Mountain Valley Project and Equitrans Expansion Project, Review Period Ends: 07/31/2017, Contact: Paul Friedman 202–502–8059.

EIS No. 20170114, Draft, USN, VA, Atlantic Fleet Training and Testing, Comment Period Ends: 08/14/2017, Contact: Todd Kraft 757–836–2943.

EIS No. 20170115, Final, USFS, WV, ADOPTION—Mountain Valley Project and Equitrans Expansion Project, Contact: Karen Overcash 540–265–5175.

The U.S. Department of Agriculture's Forest Service (USFS) has adopted the Federal Energy Regulatory Commission's FEIS #20170113, filed with EPA 06/22/2017. The USFS was a cooperating agency for this project.

Therefore, re-circulation of the document is not necessary under Section 1506.3(c) of the CEQ Regulations.

EIS No. 20170116, Final, USFS, OR, ADOPTION—Proposed Land Use Plan Amendment for the Boardman to Hemingway Transmission Line Project, Contact: Arlene Blumton 541–962–8522

The U.S. Department of Agriculture's Forest Service (USFS) has adopted the U.S. Department of the Interior's Bureau of Land Management's FEIS #20160278, filed with EPA 11/18/2016. The USFS was a cooperating agency for this project. Therefore, re-circulation of this document is not necessary under Section 1506.3(c) of the CEQ Regulations.

Amended Notices

EIS No. 20110386, Draft Supplement, USFS, ID, WITHDRAWN—Upper Lochsa Land Exchange Project, Comment Period Ends: 02/16/2012, Contact: Teresa Trulock 208–935–4256.

Revision to FR Notice Published 01/13/2012; Officially Withdrawn per request of the U.S. Forest Service.

EIS No. 20170109, Final, BLM, AZ, WITHDRAWN—Sonoran Desert National Monument Target Shooting Proposed Resource Management Plan Amendment, Review Period Ends: 07/24/2017, Contact: Wayne Monger 623–580–5683.

Revision to FR Notice Published 06/23/2017; Officially Withdrawn per request of the Bureau Land Management.

Dated: June 27, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–13831 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[9963–90–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Idaho

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Idaho's request to revise its National Primary Drinking Water Regulations Implementation EPA-authorized program to allow electronic reporting.

DATES: EPA's approval is effective July 31, 2017 for the State of Idaho's National Primary Drinking Water Regulations Implementation program, if no timely request for a public hearing is received and accepted by the Agency.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On May 5, 2017, the Idaho Department of Environmental Quality (IDEQ) submitted an application titled Compliance Monitoring Data Portal for revision to its EPA-approved drinking water program under title 40 CFR to allow new electronic reporting. EPA reviewed IDEQ's request to revise its EPA-authorized program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Idaho's request to revise its Part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting under 40 CFR part 141 is being published in the **Federal Register**.

IDEQ was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Also, in today's notice, EPA is informing interested persons that they may request a public hearing on EPA's action to approve the State of Idaho's request to revise its authorized public water system program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f). Requests for a hearing must be submitted to EPA within 30 days of publication of today's **Federal Register** notice. Such requests should include the following information:

(1) The name, address and telephone number of the individual, organization or other entity requesting a hearing;

(2) a brief statement of the requesting person's interest in EPA's determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request;

(3) the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the **Federal Register** not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today's determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA's approval of the State of Idaho's request to revise its part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today's notice is published, pursuant to CROMERR section 3.1000(f)(4).

Matthew Leopard,

Director, Office of Information Management.

[FR Doc. 2017–13663 Filed 6–29–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 17–83]

Second Meeting of the Broadband Deployment Advisory Committee

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission announces and provides an agenda for the second meeting of Broadband Deployment Advisory Committee (BDAC).

DATES: Thursday, July 20, 2017, 9:30 a.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Room TW–C305, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Brian Hurley, Designated Federal Officer (DFO), at (202) 418–2220 or *brian.hurley@fcc.gov;* or Paul D'Ari, Deputy DFO, at (202) 418–1550 or *paul.dari@fcc.gov.* The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This meeting is open to members of the general public. The FCC will accommodate as many participants as possible; however, admittance will be limited to seating availability. The Commission will also provide audio and/or video coverage of the meeting over the Internet from the FCC's Web page at *www.fcc.gov/live.* Oral statements at the meeting by parties or entities not represented on the BDAC will be permitted to the extent time permits, at the discretion of the BDAC Chair and the DFO. Members of the public may submit comments to the BDAC in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the BDAC should be filed in Docket 17–83.

Open captioning will be provided for this event. Other reasonable accommodations for people with

disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the FCC to contact the requester if more information is needed to fill the request. Please allow at least five days' advance notice; last minute requests will be accepted but may not be possible to accommodate.

Proposed Agenda: At this meeting, the BDAC Working Groups will report on their progress in developing recommendations for the BDAC's consideration. The BDAC also will continue its discussions on how to accelerate the deployment of broadband by reducing and/or removing regulatory barriers to infrastructure investment. This agenda may be modified at the discretion of the BDAC Chair and the DFO.

Federal Communications Commission.

Daniel Kahn,

Chief, Competition Policy Division, Wireline Competition Bureau.

[FR Doc. 2017–13687 Filed 6–29–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 July 28, 2017.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *WB&T Bankshares, Inc.,* Waycross, Georgia; to acquire 100 percent of the outstanding shares of Pelham Banking Company, Pelham, Georgia.

Board of Governors of the Federal Reserve System, June 27, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–13788 Filed 6–29–17; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan 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 application also will 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 HOLA (12 U.S.C. 1467a(e)). 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 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). 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 July 28, 2017.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Charter Financial Corporation,* West Point, Georgia; to become a bank holding company by merging with Resurgens Bancorp, and thereby acquiring Resurgens Bank, both of Tucker, Georgia.

In connection with this proposal, Charter Financial will retain ownership of its savings association subsidiary, CharterBank, West Point, Georgia, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii). Finally, Charter Financial will revert to savings and loan holding company status after the merger of Resurgens Bank with and into CharterBank.

Board of Governors of the Federal Reserve System, June 27, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–13787 Filed 6–29–17; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–17CA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted 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 notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the

burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Positive Health Check Evaluation Trial—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

HIV transmission continues to be an urgent public health challenge in the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 1.2 million people are living with HIV, with close to 50,000 new cases each year. Antiretroviral therapy (ART) suppresses the plasma HIV viral load (VL) and people living with HIV (PLWH) who are treated with ART—compared with those who are not—have enhanced clinical outcomes and a substantially reduced risk of transmitting HIV sexually, through drug sharing, or from mother to child. However, it is estimated that only 30% of people who are infected with HIV in the United States have an undetectable HIV VL. To enhance HIV prevention efforts, implementable, effective, scalable interventions are needed that focus on enhancing prevention and care to improve the health of and reduce HIV transmission risk among PLWH. The Positive Health Check (PHC) intervention is based on earlier computer-based interventions that were proven efficacious for HIV prevention.

The PHC intervention approach is innovative in multiple ways. First, it uses an interactive video doctor to deliver tailored messages that meet specific patient needs related to ART initiation, adherence, sexual risk reduction, engagement in care, mother-to-child transmission, and drug use. Second, this intervention is designed specifically to support improved health outcomes by providing useful behavior-change tips for patients to practice between clinic visits. These tips are generated by the tool and selected by the patient and populated on a handout that is delivered to the patient upon completing the PHC intervention. The handout has no patient-identifying information. Third, PHC supports patient-provider communication by also generating a set of questions that patients may select to ask their provider. These PHC behavior-change tips and questions are populated on a Patient Handout to guide patients' conversations with their providers and if desired, patients may choose to share their handout with their provider. As such, PHC supports the interactions between patients and their providers during their clinical encounter and is intended to improve communication. Finally, the PHC intervention has been designed from the onset for wide-scale dissemination. This web-based intervention can be easily updated and is accessible on multiple mobile devices and platforms. This approach makes PHC an important intervention strategy to improve public health in communities that have a high incidence of HIV infection.

The PHC Evaluation Trial has four primary aims: (1.) Implement a randomized trial to test the effectiveness of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care; (2.) Conduct a feasibility assessment to determine strategies to facilitate implementation and integration of PHC into the workflow of HIV primary care clinics; (3.) Collect and document data on the cost of PHC intervention implementation; and (4.) Document the standard of care at each participating clinic. The awardee of this cooperative agreement—Research Triangle International (RTI)—has subcontracted with four clinical sites to implement the trial (Atlanta VA Medical Center (Atlanta, GA), Hillsborough County Health Department (Tampa, FL), Rutgers Infectious Disease Clinic (Newark, NJ) and Crescent Care (New Orleans, LA). The four clinical sites) are well suited for this work, given the high rates of patients with elevated viral loads.

During the 36-month study period, 1,010 patients will be enrolled into the trial (505 intervention arm and 505 control arm) across the four clinics to evaluate the effectiveness of the PHC intervention. Upon enrollment, participants will be asked their date of diagnosis. To assess the effectiveness of the PHC intervention (Aim 1), patients randomized to the intervention arm will provide their responses to the patient tailoring questions embedded within the intervention and all enrolled patients will consent to have their de-identified clinical values be made available via passive data collection via the electronic medical record (EMR). In addition to the main trial, three to five key staff at each clinic site will be selected to participate in the PHC feasibility assessment (Aim 2) which includes an online survey and qualitative interviews. Clinic staff will provide data on the cost of implementing the PHC intervention (Aim 3). Finally, the medical director of each clinic will collect data on their clinic's standard of care (Aim 4).

OMB approval is requested for three years. Participation in this study is voluntary. The total estimated annualized burden hours are 419.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Patients Enrolled in the PHC Evaluation Trial	Date of diagnosis question	337	1	1/60
	PHC tailoring questions	168	3	5/60
Staff in PHC Evaluation Clinics	Electronic Medical Record (EMR)	4	4	16
	Online clinic staff survey	20	4	15/60
	Clinic staff qualitative interview	20	4	40/60
	Non-research labor cost questionnaire.	4	1	1.5

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	PHC labor cost questionnaire	4	1	1.5
	Standard of Care Questionnaire	4	1	1.5
	PHC non-labor cost questionnaire ..	4	12	30/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–13735 Filed 6–29–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2431–N2]

Medicaid Program: Zika Health Care Services Program—Round 2

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the April 7, 2017 posting of a funding opportunity for Round Two of the Zika Health Care Services Program which provides up to $6.45 million to support prevention activities and treatment services for health conditions related to the Zika virus for entities that meet the eligibility requirements of the Zika Health Care Services Program, but that did not receive an award under the Round One Funding Opportunity. The Round Two Funding Opportunity provides two application due dates, May 8, 2017 and July 10, 2017. Entities eligible to apply for this funding opportunity are states, territories, tribes or tribal organizations, with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC).

DATES: The project period of performance for the Cooperative Agreement will be 36 months from the date of award.

FOR FURTHER INFORMATION CONTACT: Elizabeth Garbarczyk, 410–786–0426.

SUPPLEMENTARY INFORMATION:

I. Background

The Zika Response and Preparedness Act (Pub. L. 114–223) provides $387,000,000 in funding to prevent, prepare for, and respond to the Zika virus. Of the funds appropriated by Public Law (Pub. L.) 114–223, Congress designated $75 million to support states, territories, tribes, or tribal organizations with active or local transmission cases of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC), to reimburse the costs of health care for health conditions related to the Zika virus not covered by private insurance. No less than $60 million of this funding is for territories with the highest rates of Zika transmission.

The Zika Health Care Services Program funding opportunities solicit single source emergency applications for a cooperative agreement aimed at supporting prevention activities and treatment services for women (including pregnant women), children, and men adversely or potentially impacted by the Zika virus.

On January 18, 2017, CMS issued $66.1 million in awards to eligible entities that applied for Round One of the Zika Health Care Services Program (American Samoa, Puerto Rico, U.S. Virgin Islands, and Florida). The Round One Funding Opportunity sought to issue funds to areas of greatest need, while maintaining additional funds to prevent, detect, and respond to future Zika outbreaks.

II. Provisions of the Notice

In accordance with the Zika Response and Preparedness Act (Pub. L. 114–223), entities eligible to apply for this funding opportunity include states, territories, tribes or tribal organizations with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC). Recipients who previously received a Notice of Award under Round One of the Zika Health Care Services Program, Funding Opportunity Number CMS–1Q1–17–001, are not eligible to apply. As of the first application due date, May 8, 2017, the CDC reports that Texas is the only new area with laboratory-confirmed active or local transmission of the Zika virus; and therefore, this is the only state currently eligible to receive funding as authorized under the legislation.

This funding opportunity has been structured to ensure a comprehensive response to Zika as quickly as possible. Accordingly, the single-source emergency funding opportunity is solely available to the state health department in Texas, based on its ability to quickly and efficiently expand its existing Zika response efforts and to further determine the most effective use and dissemination of funds in its respective jurisdictions. The health department in Texas is uniquely positioned to meet the goals of the emergency cooperative agreement based on its capacity, partnerships, resources, prior experience, and ability to begin implementing the project immediately. Immediate implementation is critical to successfully addressing this rapidly spreading public health threat. The budget and project period under the specific funding opportunity will be 36 months. The total amount of federal funds available in Round Two, for both the May 8, 2017 and July 10, 2017 due dates, is up to $6.45 million. The Texas Department of State Health Services submitted their application, and was the only entity eligible for an award as of the May 8, 2017 application due date. The proposed award amount is $1,800,000.

The second application due date for the Round Two Funding Opportunity is July 10, 2017. Eligibility for the second Round Two application due date is based on the state, territory, tribe, or tribal organization meeting all of the following criteria:

- Has active or local transmission cases of the Zika virus, as confirmed by the CDC.
- Did not receive an award in Round One.
- Has not received a response to an application submitted by the first application due date (May 8, 2017).

III. Collection of Information Requirements

This notice establishes funding opportunities for health departments in areas with laboratory-confirmed active or local Zika virus transmission. The funding opportunity application process constitutes an information collection request. Specifically, this notice

pertains to Round Two for which there is only one eligible respondent (Texas). There were 4 total respondents in Round 1 (American Samoa, Puerto Rico, U.S. Virgin Islands, and Florida). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(c)(4), we estimate the total number of respondents between Round One and Round Two will not exceed 10 in a 12-month period. Therefore, the associated burden is exempt from the requirements of the PRA (44 U.S.C. 3501 *et seq.*).

Dated: June 13, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–13784 Filed 6–29–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10393]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *July 31, 2017.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs; Attention: CMS Desk Officer; Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension, revision or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Beneficiary and Family Centered Data Collection; *Use:* The CMS Quality Improvement Organization (QIO) Program includes Beneficiary and Family Centered Care (BFCC) QIOs whose functions, as set forth in Section 1862(g) of the Social Security Act, are to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. To accomplish these goals, the QIOs review health care services funded under Medicare to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and meet professionally recognized standards of quality. The QIOs also review health care services where the beneficiary or a representative has complained about the quality of those services or is appealing alleged premature discharge.

Under the current 11th QIO Statement of Work (SOW), two organizations are providing services as BFCC QIOs across all of the United States. The QIO evaluation criteria have been revised to reflect this national regionalization and it is important for CMS to understand the impact on beneficiaries from this reorganization. The information will be used to evaluate the success of each QIO in meeting its contractual requirements and to understand the experience of Medicare beneficiaries and/or their representative with QIO contract mandated work. *Form Number:* CMS–10393 (OMB control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 24,970; *Number of Responses:* 24,970; *Total Annual Hours:* 2,899. (For policy questions regarding this collection, contact David Russo at 617–565–1310.)

Dated: June 27, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–13835 Filed 6–29–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3345–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—August 30, 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, August 30, 2017. This meeting will specifically focus on obtaining the MEDCAC's recommendations regarding the appraisal of the state of evidence for health outcomes in the Medicare population for surgical and endoscopic procedures for weight loss. This meeting is open to the public in accordance with the Federal Advisory Committee Act.

DATES: *Meeting Date:* The public meeting will be held on Wednesday, August 30, 2017 from 7:30 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5:00 p.m., EDT, Monday, July 24, 2017. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EDT on Monday, July 24, 2017. Speakers may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5:00 p.m. EDT, Wednesday, August 23, 2017. We will be broadcasting the meeting live via Webcast at *http://www.cms.gov/live/.*

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EDT Friday, August 4, 2017.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via email to *MedCACpresentations@cms.hhs.gov* or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via email at *Maria.Ellis@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MCAC, see the MEDCAC Charter (*http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf*) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC* (*http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10*)).

II. Meeting Topic and Format

This notice announces the Wednesday, August 30, 2017, public meeting of the Committee. During this meeting, the Committee will discuss recommendations regarding the appraisal of the state of evidence for health outcomes in the Medicare population for surgical and endoscopic procedures for weight loss. Background information about this topic, including panel materials, is available at *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of organizations with expertise in health outcomes in the Medicare population for surgical and endoscopic procedures for weight loss. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 31, 2017. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting should include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association < $10,000 or major association > $10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics

under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), fax number, and email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at *http://www.dhs.gov/real-id-enforcement-brief.* We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

V. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: June 22, 2017.

Kate Goodrich,

Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–13785 Filed 6–29–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0422]

Proposed Information Collection Activity; Comment Request

Title: Adoption and Foster Care Analysis Reporting System for title IV–B and title IV–E (AFCARS).

Description: The Adoption and Foster Care Analysis and Reporting System (AFCARS) is mandated by 42 U.S.C. 679. The regulation at 45 CFR 1355 sets forth the requirements of section 479 of the Social Security Act for the collection of uniform, reliable information on children who are under the responsibility of the State or Tribal title IV–B/IV–E agency for placement, care, and adoption. Effective October 1, 2009, section 479B(b) of the Act authorizes direct Federal funding of Indian Tribes, Tribal organizations, and Tribal consortia that choose to operate a foster care, adoption assistance and, at Tribal option, a kinship guardianship assistance program under title IV–E of the Act. The data collected per the requirements at 45 CFR 1355.40 will end September 30, 2019. On October 1, 2019 the data collection will be replaced by the requirements in 45 CFR 1355.41—44, as reflected in the final rule published in the **Federal Register** on December 14, 2016 (81 FR 90524).

The data collected will inform State/Tribal/Federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data are used for short/long-term budget projections, trend analysis, child and family service reviews, and to target areas for improved technical assistance. The data will provide information about foster care placements, adoptive parents, length of time in care, delays in termination of parental rights and placement for adoption.

Respondents: Title IV–E State and Tribal Child Welfare Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS	59	2	2,188	258,215

Estimated Total Annual Burden Hours: 258,215.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–13726 Filed 6–29–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3224]

Authorization of Emergency Use of an Injectable Treatment for Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an injectable treatment for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the U.S. Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized injectable treatment. The Authorization follows the April 11, 2017, determination by the Department of Health and Human Services (HHS) Secretary that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate). On the basis of such determination, the HHS Secretary declared on April 11, 2017, that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of April 11, 2017.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances

exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the CDC (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Request for an Injectable Treatment for Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning

On April 11, 2017, under section 564(b)(1)(C) of the FD&C Act, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate). On April 11, 2017, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on April 17, 2017 (82 FR 18152). On March 9, 2017, CDC requested, and on April 11, 2017, FDA issued, an EUA for the 2 mg Rafa Atropine Auto-Injector, manufactured by Rafa Laboratories Ltd., subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *https://www.regulations.gov.*

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an injectable treatment for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act.

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 11, 2017

Anne Schuchat, M.D. (RADM, USPHS)
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Schuchat:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Rafa Laboratories Ltd. (Rafa) Atropine Auto-Injector for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population (as described in the Scope of Authorization section of this letter (Section II)), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1]

On April 11, 2017, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate).[2] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[3]

The Centers for Disease Control and Prevention (CDC) requested this EUA so that the Rafa Atropine Auto-Injector, which is not FDA-approved, may be distributed and held by CDC,

[1] At the time of issuance of this Emergency Use Authorization (EUA), the Rafa Atropine Auto-Injector was approved in at least one country (i.e., Israel) but not approved in the U.S. This EUA, including its Conditions of Authorization in Section IV, applies only to Rafa Atropine Auto-Injector product that is manufactured and distributed by Rafa and its authorized agent(s) specifically for U.S. Government procurement and further distribution, stockpiling, and use during an emergency as set forth in this authorization.

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[3] U.S. Department of Health and Human Services (HHS). *Determination of a Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).* April 11, 2017.

emergency response stakeholders, and DoD for preparedness purposes in advance of an actual nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning event, with the intent that it may be administered by healthcare providers or caregivers, or be self-administered, during an event or post-event for treatment of the muscarinic symptoms of poisoning caused by exposure to these agents.[4] An EUA is needed to facilitate CDC, emergency response stakeholder, and DoD pre-event planning and preparedness activities related to the use of this unapproved product to enable activities to support rapid administration of treatment during an actual emergency event involving nerve agents or certain insecticides (organophosphorus and/or carbamate) (e.g., distribution and use of fact sheets about the product, pre-event distribution and stockpiling of an unapproved product, administration of an unapproved product without a prescription, and administration by individuals who are not licensed professionally to administer the product). This EUA is important for emergency response purposes because it enables rapid initiation of treatment with the Rafa Atropine Auto-Injector during a nerve agent or insecticide emergency without FDA and CDC, emergency response stakeholders, or DoD having to take further action with respect to otherwise applicable requirements under federal law.

Other atropine auto-injectors previously have been approved by FDA to treat nerve agent and insecticide poisoning in adults and children. However, at the time of issuance of this EUA, FDA-approved atropine auto-injectors for the treatment of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning were not available to replenish the Department's Strategic National Stockpile inventory when the products in the current inventory expire.[5] This EUA will help to facilitate the fulfillment of national preparedness and stockpiling requirements and needs for new atropine auto-injectors.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Rafa Atropine Auto-Injector (as described in the Scope of Authorization section of this letter (Section II)) in the specified population (as described in the Scope of Authorization section of this letter (Section II)) for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate), subject to the terms of this authorization.

This EUA applies in all circumstances when CDC, emergency response stakeholders, and/or DoD reasonably believe that there is a need to store, distribute, and/or administer the authorized Rafa Atropine Auto-Injector without an individual prescription in an emergency because of their constituents' known, suspected, or likely imminent exposure to nerve agents or certain insecticides (organophosphorus and/or carbamate).[6]

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[4] For purposes of this EUA, the term "emergency response stakeholders" refers to CHEMPACK stakeholders (as defined by the Centers for Disease Control and Prevention (CDC)/Division of Strategic National Stockpile (SNS) under the CHEMPACK program), and to other public health, emergency response, and/or other government agencies that receive the authorized Rafa Atropine Auto-Injector through CDC, and that have legal responsibility and authority for responding to an incident, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

[5] Regarding the SNS, see 42 U.S.C. § 247d-6b(a).

[6] For purposes of this EUA, the terms "administer" and "administration" refer to administration of the authorized Rafa Atropine Auto-Injector by healthcare providers and caregivers (as defined later in this letter) and by individuals administering the authorized Rafa Atropine Auto-Injector to themselves (i.e., self-administration) when healthcare

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Rafa Atropine Auto-Injector for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population (as described in the Scope of Authorization section of this letter (Section II)) meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. Susceptible nerve agents and certain insecticides (organophosphorus and/or carbamate) can cause muscarinic symptoms of poisoning, a serious or life-threatening disease or condition to humans exposed to these agents or insecticides;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Rafa Atropine Auto-Injector, when used in accordance with the Scope of Authorization, may be effective for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate), and that the known and potential benefits of the Rafa Atropine Auto-Injector for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Rafa Atropine Auto-Injector for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate).[7]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Rafa Atropine Auto-Injector by CDC, emergency response stakeholders, and DoD for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population (see below). The emergency use of the authorized Rafa Atropine Auto-Injector product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The Authorized Rafa Atropine Auto-Injector:

I am authorizing the use of the 2 mg Rafa Atropine Auto-Injector. The 2 mg Rafa Atropine Auto-Injector is a combination product (drug/device) to provide initial treatment of the muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in adults and children (weighing over 41 kg (90 lbs) (generally over 10 years of age)) following an intentional terrorism-related or unintentional event.[8] CDC may request the authorization of additional strengths (e.g., 0.5 mg and/or 1 mg) of

providers and caregivers are not available to administer the authorized Rafa Atropine Auto-Injector.

[7] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[8] Treatment and management of nerve agent and insecticide (organophosphorus and/or carbamate) poisoning include decontamination, supportive measures, and repeated administration of antidotes. Atropine is an antimuscarinic

the Rafa Atropine Auto-Injector, which may be authorized by FDA in consultation with, and with concurrence of, the Division of Neurology Products (DNP)/Office of Drug Evaluation I (ODE1)/Office of New Drugs (OND)/Center for Drug Evaluation and Research (CDER), the Counter-Terrorism and Emergency Coordination Staff (CTECS)/Office of the Center Director (OCD)/CDER, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).[9]

The authorized Rafa Atropine Auto-Injector is a self-contained unit specially designed for automatic healthcare provider,[10] caregiver,[11] or individual (i.e., self) administration. Each pre-filled auto-injector provides a single dose of atropine. When activated, the authorized 2 mg Rafa Atropine Auto-Injector dispenses 1.67 mg atropine base (equivalent to 2 mg atropine sulfate) in 0.7 mL of sterile pyrogen-free solution through a single needle for rapid intramuscular (IM) administration.

The authorized 2 mg Rafa Atropine Auto-Injector, and any other strengths that are authorized at a later time under this EUA, are authorized to be distributed by CDC, emergency response stakeholders, and DoD for pre-event storage and further redistribution, if appropriate, and for post-event storage, distribution, and administration, when packaged in the authorized manufacturer packaging and with the authorized labeling (e.g., the labels on each auto-injector and box carton, including expiration date, National Drug Code, National Stock Number if needed, bar code, and lot number; and fact sheets), despite the fact that they may not contain information on the prescription label that otherwise would be required under section 503(b)(2) of the Act (21 U.S.C. § 353(b)(2)) (e.g., name and address of dispenser; serial number; date of prescription or of its filling; name of prescriber; name of patient, if stated on prescription;

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agent that antagonizes the muscarine-like actions of acetylcholine and other choline esters. Atropine inhibits the muscarinic actions of acetylcholine on structures innervated by postganglionic cholinergic nerves, on smooth muscles, which respond to endogenous acetylcholine but are not so innervated, and on brain. As with other antimuscarinic agents, the major action of atropine is a competitive or surmountable antagonism, which can be overcome by increasing the concentration of acetylcholine at receptor sites of the effector organ (e.g., by using anticholinesterase agents, which inhibit the enzymatic destruction of acetylcholine). When atropine and pralidoxime (2-PAM) are co-administered, survival is improved due to their synergistic effects.

[9] On the date of issuance of this EUA, the 0.5 mg Rafa Atropine Auto-Injector and 1 mg Rafa Atropine Auto-Injector were not authorized for use under this EUA. However, CDC may request authorization under this EUA of the 0.5 mg and 1 mg strengths at a later time. If FDA authorizes use of the 0.5 mg and 1 mg strengths based on a review of the scientific data, communication about such authorization will be posted on FDA's EUA website at the time of amendment of this EUA (e.g., through a memorandum and updated EUA Fact Sheets). https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

[10] For purposes of this EUA, the term "healthcare provider" includes (i) healthcare professionals who are acting within their professional scope of practice; (ii) healthcare professionals who might otherwise be acting outside of their professional scope of practice in administering the authorized Rafa Atropine Auto-Injector (e.g., physicians not licensed in the state; certain emergency medical technicians, paramedics, physician assistants, nurses, pharmacists, etc.); and (iii) other responders (e.g., firefighters). To the extent feasible and appropriate, healthcare providers should be acting under the authority of the applicable emergency response stakeholder's authority and official emergency response plans when administering the authorized product.

[11] For purposes of this EUA, the term "caregiver" includes individuals who are not healthcare providers as defined in this EUA (e.g., public health agency staff, military service members, volunteers, agents, contractors, family members, co-workers, bystanders, etc.), but who might be the only available individual to administer the Rafa Atropine Auto-Injector to an individual exhibiting symptoms of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning (e.g., if the demand for patient care exceeds the capacity of available healthcare providers during an emergency response). To the extent feasible and appropriate, caregivers should be acting under the authority of the applicable emergency response stakeholder's official emergency response plans when receiving and administering the authorized product.

directions for use and cautionary statements, if contained in the prescription).

The authorized Rafa Atropine Auto-Injector is authorized to be administered without a prescription and by healthcare providers, caregivers, and individuals (i.e., to oneself) under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The authorized Rafa Atropine Auto-Injector is authorized to be accompanied by the authorized manufacturer's labeling (e.g., the labels on each auto-injector and box carton) developed in consultation with FDA and CDC. The authorized Rafa Atropine Auto-Injector is also authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers, caregivers, and individuals/patients[12] to facilitate understanding of nerve agent and certain insecticide (organophosphorus and/or carbamate) poisoning, the risks and benefits of the Rafa Atropine Auto-Injector, and proper medication administration:

- Fact Sheet for Healthcare Providers: Use of the 2 mg Rafa Atropine Auto-Injector for Initial Treatment of Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning

- Fact Sheet for Patients and Caregivers: Use of the 2 mg Rafa Atropine Auto-Injector for Initial Treatment of Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning

Other Fact Sheets developed by CDC and/or by DoD (e.g., specifically for DoD purposes) in consultation with, and with concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC may be authorized to accompany the above described Rafa Atropine Auto-Injector and to be made available to healthcare providers, caregivers, and individuals/patients, as appropriate.

As described in Section IV below, CDC and DoD are also authorized to make available additional information relating to the emergency use of the authorized Rafa Atropine Auto-Injector that is reasonably consistent with, and does not exceed, the terms of this letter of authorization.

Authorized Rafa Atropine Auto-Injectors are authorized to have their manufacturer labeled expiry dating extended by DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC based on scientific data supporting such an extension.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Rafa Atropine Auto-Injector in the specified population, when used for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and

[12] The authorized Fact Sheet for Patients and Caregivers includes information for (i) patients to whom the authorized Rafa Atropine Auto-Injector is administered by healthcare providers or caregivers, (ii) individuals who may need to self-administer the authorized Rafa Atropine Auto-Injector, and (iii) caregivers who may need to administer the authorized Rafa Atropine Auto-Injector to individuals.

potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Rafa Atropine Auto-Injector may be effective in the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate), when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized Rafa Atropine Auto-Injector, when used for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Rafa Atropine Auto-Injector under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Rafa Atropine Auto-Injector described above is authorized for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

This letter authorizes use of Rafa Atropine Auto-Injectors as previously manufactured by Rafa under U.S. Government contract as of the date of this letter, as well as authorized Rafa Atropine Auto-Injectors that may be manufactured by Rafa under U.S. Government contract after such date, insofar as the informational visit and testing completed on production quality products provide reasonable assurance that the methods used in, and the facilities and controls used for, the manufacturing, processing, labeling, and packing of the authorized Rafa Atropine Auto-Injector are adequate to preserve its identity, strength, quality, and purity for use of the product under this EUA.

The authorized Rafa Atropine Auto-Injector should be held in accordance with the manufacturer's labeled and appropriate product storage conditions for the product (i.e., ambient temperature, 25°C (77°F), with excursions permitted to 15°C-30°C (59°F-86°F)). In addition, the USP allows for a brief excursion to higher temperatures (i.e., up to 24 hours at up to 40°C (104°F)). However, to ensure the delivery and availability of the authorized Rafa Atropine Auto-Injector in the event of a nerve agent or certain insecticide (organophosphorus and/or carbamate) emergency and a decision on the part of CDC, an emergency response stakeholder(s), or DoD to distribute and administer the product under the terms of this EUA, the authorized Rafa Atropine Auto-Injector may require transportation and/or temporary storage for rapid

administration without the capacity to maintain labeled storage conditions in the midst of the response. During such scenarios, the authorized Rafa Atropine Auto-Injector may be stored with temperature excursions up to 40°C (104°F) for a total period of up to 7 days. Significant excursions from the labeled storage conditions should be documented to the extent practicable given the circumstances of an emergency.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will distribute the authorized Rafa Atropine Auto-Injector under its direction to the extent such decisions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling.

B. Through a process of inventory control, CDC will maintain records regarding distribution under its direction of the authorized Rafa Atropine Auto-Injector (i.e., lot numbers, quantity, receiving site, receipt date).

C. CDC will ensure that the terms of this EUA are made available to emergency response stakeholders and DoD through appropriate means.[13] CDC will provide authorized emergency response stakeholders and DoD a copy of this letter of authorization, and communicate to emergency response stakeholders and DoD any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., Fact Sheets).

D. CDC will make available to emergency response stakeholders and DoD through appropriate means the authorized Rafa Atropine Auto-Injector Fact Sheet for Healthcare Providers, the authorized Rafa Atropine Auto-Injector Fact Sheet for Patients and Caregivers, and any other Fact Sheets for emergency response stakeholders that FDA may authorize, as well as any authorized amendments thereto.

E. CDC may request changes to the authorized Rafa Atropine Auto-Injector Fact Sheet for Healthcare Providers and the authorized Rafa Atropine Auto-Injector Fact Sheet for Patients and Caregivers and may request the development of additional Fact Sheets. Such requests will be made by CDC in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

F. CDC is authorized to issue additional recommendations and instructions related to the emergency use of the authorized Rafa Atropine Auto-Injector as described in this letter of authorization, to the extent that additional recommendations and instructions are necessary to meet public health needs during an event involving susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) and are reasonably consistent with the authorized emergency use of the product.

[13] For example, through hard copy, web posting, and/or mass media.

G. CDC may request changes to the authorized manufacturer's labeling (e.g., the labels on each auto-injector and carton) for the authorized Rafa Atropine Auto-Injector, or to the manufacturing, labeling, and packaging processes of Rafa or its authorized agent(s) for the authorized product. Such requests will be made by CDC in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

H. CDC may request the authorization of additional strengths (e.g., 0.5 mg and 1 mg) of the authorized Rafa Atropine Auto-Injector under this EUA. Such requests will be made by CDC in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

I. CDC will inform emergency response stakeholders about the need to have a process in place for performing adverse event monitoring and compliance activities designed to ensure that adverse events and all medication errors associated with the use of the authorized Rafa Atropine Auto-Injector are reported to FDA, to the extent practicable given emergency circumstances, as follows: complete the MedWatch FDA Form 3500 online at www.fda.gov/medwatch, by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088. Submitted reports should state that the Rafa Atropine Auto-Injector was used under an EUA and should provide the strength (e.g., 2 mg) that was administered. CDC will conduct any follow-up requested by FDA regarding adverse events, to the extent feasible given the emergency circumstances.

J. CDC will ensure that the authorized Rafa Atropine Auto-Injector is distributed for use under its direction within the expiry dating on the manufacturer's labeling. If FDA authorizes any expiry dating extensions of the authorized Rafa Atropine Auto-Injector under this EUA, CDC will inform emergency response stakeholders and DoD receiving the authorized Rafa Atropine Auto-Injector of such extensions and any conditions related to such extensions under this EUA. CDC will maintain adequate records regarding the expiry dates by which authorized Rafa Atropine Auto-Injectors may be used.

K. CDC will make available to FDA upon request any records maintained in connection with this EUA.

Emergency Response Stakeholders to Whom the Authorized Rafa Atropine Auto-Injector Is Distributed

L. Emergency response stakeholders will inform their applicable healthcare providers[14] of this letter of authorization, including the terms herein, and of any subsequent amendments that might be made to this letter of authorization and its authorized

[14] As defined earlier, for purposes of this EUA, the term "healthcare provider" includes (i) healthcare professionals who are acting within their professional scope of practice; (ii) healthcare professionals who might otherwise be acting outside of their professional scope of practice in administering the Rafa Atropine Auto-Injector (e.g., physicians not licensed in the state; certain emergency medical technicians, paramedics, physician assistants, nurses, pharmacists, etc.); and (iii) other responders (e.g., firefighters). To the extent feasible and appropriate, healthcare providers should be acting under the authority of the applicable emergency response stakeholder's authority and official emergency response plans when administering the authorized product.

accompanying materials (e.g., Fact Sheets), through appropriate means.

M. Emergency response stakeholders will inform their applicable healthcare providers that the authorized Rafa Atropine Auto-Injector may be used only for the initial treatment of the muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population.

N. Emergency response stakeholders will ensure that their applicable healthcare providers administering the authorized Rafa Atropine Auto-Injector will abide by any procedures regarding drug accountability issued by CDC and/or their respective institutions.

O. Through a process of inventory control, emergency response stakeholders will maintain records of product usage (i.e., lot number, quantity, receiving site, receipt date, and administration date), product storage, and disposition of the authorized product and will maintain records regarding further distribution (if permissible) under their direction of the authorized Rafa Atropine Auto-Injector product.

P. Emergency response stakeholders will, consistent with any applicable CDC and/or jurisdictional procedures, be responsible for authorizing their applicable healthcare providers to administer the authorized Rafa Atropine Auto-Injector in accordance with the terms of this letter of authorization, including instructing their applicable healthcare providers about the terms of this letter of authorization with regard to pre-event storage and distribution and post-event storage, distribution, and administration, and for instructing them about the means through which they are to obtain the authorized Rafa Atropine Auto-Injector.[15]

Q. Emergency response stakeholders will include with the authorized Rafa Atropine Auto-Injector the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and Caregivers, and any other Fact Sheets for emergency response stakeholders that FDA may authorize, as well as any authorized amendments thereto. Under exigent circumstances, these Fact Sheets may be disseminated through other appropriate means (e.g., web posting, mass media). With the exception of DoD-specific Fact Sheets (see Condition FF), changes to the authorized Fact Sheets may be made only by CDC in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

R. Emergency response stakeholders will train their applicable healthcare providers on the use of the authorized Rafa Atropine Auto-Injector in accordance with this EUA and any applicable institutional procedures or protocols. In the event of an emergency during which the authorized Rafa Atropine Auto-Injector may need to be administered by caregivers and/or be self-administered, emergency response stakeholders will inform such caregivers and individuals about the use of the authorized product (e.g., by providing them with the Fact Sheet for Patients and Caregivers and/or just-in-time

[15] An emergency response stakeholder may also, if permitted by CDC, distribute the authorized product to other public or private entities acting as the agents or delegates of the emergency response stakeholder as part of a public health or medical response. If such distribution occurs, the emergency response stakeholder will be responsible for ensuring that the authorized agents and/or delegates adhere to the emergency response stakeholder conditions and any applicable healthcare provider conditions provided in this letter of authorization.

training, instructing healthcare providers how to inform patients and caregivers, etc.), to the extent feasible given the emergency circumstances.[16]

S. Emergency response stakeholders will track adverse events and report to FDA in accordance with the Fact Sheet for Healthcare Providers (i.e., complete the MedWatch FDA Form 3500 online at www.fda.gov/medwatch, by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088; submitted reports should state that the Rafa Atropine Auto-Injector was used under an EUA and should provide the strength (e.g., 2 mg) that was administered), to the extent feasible given the emergency circumstances. Emergency response stakeholders will conduct any follow-up requested by FDA and/or CDC regarding adverse events, to the extent feasible given the emergency circumstances.

T. Emergency response stakeholders will track and communicate, to the extent appropriate, any expiry dating extensions of the authorized Rafa Atropine Auto-Injector that FDA may authorize, and that CDC may communicate, under this EUA and any conditions related to such extensions under this EUA. Emergency response stakeholders will maintain adequate records regarding the expiry dates by which authorized Rafa Atropine Auto-Injector may be used.

U. Emergency response stakeholders will ensure that any records associated with this EUA are maintained until notified by CDC and/or FDA. Such records will be made available to FDA and/or CDC for inspection upon request.

Healthcare Providers Conducting Activities under the Direction of Emergency Response Stakeholders with Respect to the Authorized Rafa Atropine Auto-Injector[17]

V. Healthcare providers conducting activities under the direction of emergency response stakeholders with respect to the authorized Rafa Atropine Auto-Injector will be aware of this letter, including the terms and any authorized amendments thereto. Healthcare providers will read the authorized Fact Sheet for Healthcare Providers prior to administering the authorized Rafa Atropine Auto-Injector, to the extent feasible given the emergency circumstances.

W. Healthcare providers administering the authorized Rafa Atropine Auto-Injector will ensure that the authorized Fact Sheet for Patients and Caregivers has been made available to patients and/or caregivers through appropriate means, to the extent feasible given the emergency circumstances. In the event of an emergency during which the authorized Rafa Atropine Auto-Injector may need to be administered by caregivers and/or be self-administered, healthcare providers will inform such caregivers and individuals about the use of the authorized product (e.g., by providing them with the Fact Sheet for Patients

[16] As described earlier in this letter of authorization, it is contemplated during some response scenarios that the authorized Rafa Atropine Auto-Injector may need to be administered by caregivers or be self-administered.

[17] The Conditions of Authorization for healthcare providers conducting activities under the direction of emergency response stakeholders with respect to the authorized Rafa Atropine Auto-Injector do not apply to DoD. DoD-specific Conditions of Authorization are provided below.

and Caregivers, just-in-time training, etc.), to the extent feasible given the emergency circumstances.

X. Healthcare providers will administer the authorized Rafa Atropine Auto-Injector only for the initial treatment of the muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population following an intentional terrorism-related or unintentional event.

Y. Healthcare providers will track adverse events and report to FDA in accordance with the Fact Sheet for Healthcare Providers (i.e., complete the MedWatch FDA Form 3500 online at www.fda.gov/medwatch, by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088; submitted reports should state that the Rafa Atropine Auto-Injector was used under an EUA and should provide the strength (e.g., 2 mg) that was administered), to the extent feasible given the emergency circumstances. Healthcare providers will conduct any follow-up requested by FDA and/or CDC regarding adverse events, to the extent feasible given the emergency circumstances.

Z. Healthcare providers will ensure that any records associated with the use of this product under this EUA are maintained, to the extent feasible given the emergency circumstances, until notified by FDA and/or CDC. Such records will be made available to FDA and/or CDC for inspection upon request.

DoD

AA. DoD may distribute the authorized 2 mg Rafa Atropine Auto-Injector product under its direction to DoD components to the extent such decisions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling.

BB. DoD will ensure that the terms of this EUA are made available to applicable DoD components through appropriate means. DoD will provide applicable DoD components a copy of this letter of authorization, and communicate to such components any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., Fact Sheets for DoD-only use).

CC. DoD will inform applicable DoD components that the authorized Rafa Atropine Auto-Injector may be used only for the initial treatment of the muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) in the specified population.

DD. Through a process of inventory control, DoD will maintain records regarding distribution and use under its direction of the authorized Rafa Atropine Auto-Injector (i.e., lot number, quantity, receiving site, receipt date, and administration date), product storage, and disposition of the authorized product, to the extent feasible given the emergency circumstances.

EE. DoD will make available through applicable DoD communication channels and procedures the authorized Rafa Atropine Auto-Injector Fact Sheets and/or authorized DoD-specific Rafa Atropine Auto-Injector Fact Sheet(s), as well as any authorized amendments thereto. Under exigent circumstances, other appropriate means for disseminating these Fact Sheets may be used.

FF. DoD may request the development and use of a Fact Sheet(s) for DoD-specific purposes for the authorized 2 mg Rafa Atropine Auto-Injector. Such requests will be made by DoD in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC. DoD will inform CDC of such requests. Changes to any authorized DoD-specific Rafa Atropine Auto-Injector Fact Sheets may be made only by DoD in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC. DoD will also inform CDC of such changes. Such DoD-specific Rafa Atropine Auto-Injector Fact Sheets will not be used by non-DoD emergency response stakeholders.

GG. DoD will be responsible for authorizing components acting as part of a DoD response to administer the authorized Rafa Atropine Auto-Injector in accordance with the terms of this EUA, including instructing such components about the terms of this EUA with regard to pre-event storage and distribution and post-event storage, distribution, and administration, and for instructing them about the means through which they are to obtain and use the authorized Rafa Atropine Auto-Injector.

HH. DoD is authorized to issue additional recommendations and instructions related to the DoD-specific emergency use of the authorized Rafa Atropine Auto-Injector as described in this letter of authorization, to the extent that additional recommendations and instructions are necessary to meet military needs during an event involving susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate) and are reasonably consistent with the authorized emergency use of the product.

II. DoD will train applicable DoD components and/or personnel on the use of the authorized Rafa Atropine Auto-Injector in accordance with this EUA and any applicable DoD procedures or protocols.

JJ. DoD, through applicable DoD components, will track adverse events and report to FDA (e.g., by completing the MedWatch FDA Form 3500 online at www.fda.gov/medwatch, by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088; submitted reports should state that the Rafa Atropine Auto-Injector was used under an EUA and should provide the strength (i.e., 2 mg) that was administered), to the extent feasible given the emergency circumstances. DoD will conduct any follow-up requested by FDA and/or CDC regarding adverse events, to the extent feasible given the

emergency circumstances.

KK. DoD will ensure that the authorized Rafa Atropine Auto-Injector is distributed for use under its direction within the expiry dates on the manufacturer's labeling. If FDA authorizes any expiry dating extensions of the authorized Rafa Atropine Auto-Injector under this EUA, DoD will inform DoD components receiving the authorized Rafa Atropine Auto-Injector of such extensions and any conditions related to such extensions under this EUA. DoD will maintain adequate records regarding the expiry dates by which authorized Rafa Atropine Auto-Injector may be used.

LL. DoD will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Rafa

MM. Rafa is authorized to have Shalon Chemical Industries Ltd. as its authorized agent under this EUA. Rafa may request an additional authorized agent(s) related to its production and/or distribution of the authorized Rafa Atropine Auto-Injector under this EUA. Such requests will include the name, address, phone number, and role of any proposed authorized agent(s) and will be made to FDA by CDC and/or Rafa in consultation with, and require concurrence of, DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC. Rafa will also notify FDA and CDC before beginning to use such agent(s) as may be authorized by FDA.

NN. Rafa will post on its website the following statement: "For information about the FDA-authorized emergency use of the Rafa Atropine Auto-Injector, please see: https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm." Rafa will ensure that any website references to the authorized Rafa Atropine Auto-Injector by its authorized agent(s) will include the same statement.

OO. Rafa will distribute the authorized Rafa Atropine Auto-Injector under this EUA only under U.S. Government contract to CDC and/or CDC's designee(s) and subject to terms of this letter.

PP. Rafa will contact CDC for CDC to request FDA review and concurrence before any changes are made to the manufacturer's labeling (e.g., the labels on each auto-injector and carton) for the authorized product, and before any changes are made to its manufacturing, labeling, and packaging processes, or any such processes of its authorized agent(s), for the authorized product (see Condition G).

QQ. Rafa may submit additional data to FDA through CDC to support the authorization of additional strengths of the Rafa Atropine Auto-Injector. Upon

review of this data and DNP/ODE1/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC concurrence (as described above in Condition H), Rafa and its authorized agent(s) will be authorized to manufacture and distribute under U.S. Government contract the additional strengths of the Rafa Atropine Auto-Injector subject to the terms set forth in this letter of authorization and any subsequent amendments to this letter.

RR. Rafa will promptly notify FDA and CDC of any suspected or confirmed quality, manufacturing, distribution, and/or other issues with the authorized Rafa Atropine Auto-Injector, including such issues associated with its authorized agent(s), of which it becomes aware.

SS. Rafa will make available to FDA and, as reasonably appropriate, to CDC upon request any records maintained in connection with this letter. Upon request, Rafa will report to FDA and/or, as reasonably appropriate, to CDC information on the authorized Rafa Atropine Auto-Injector (e.g., with respect to the quality, manufacturing, distribution, emergency use, etc. of the authorized product, including activities related to its authorized agent(s)).

Conditions Related to Advertising and Promotion

TT. All advertising and promotional descriptive printed matter relating to the use of the authorized Rafa Atropine Auto-Injector shall be consistent with the Fact Sheets, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

UU. All advertising and promotional descriptive printed matter relating to the use of the authorized Rafa Atropine Auto-Injector shall clearly and conspicuously state that:

- This product has not been FDA approved or cleared;
- This product has been authorized by FDA under an EUA for use by CDC, emergency response stakeholders, and DoD;
- This product has been authorized only for the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate), not for any other agents, viruses, or pathogens; and
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Rafa Atropine Auto-Injector may represent or suggest that this product is safe or effective for

Page 15 – Dr. Schuchat, CDC

the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate).

The emergency use of the authorized Rafa Atropine Auto-Injector as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: June 26, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13664 Filed 6–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug

Correction

In notice document 2017–10818 appearing on pages 24351 through 24356 in the issue of Friday, May 26, make the following correction:

On page 24351, in the third column, under the **DATES** heading, in the third line ''June 26, 2017'' should read ''July 25, 2017''.

[FR Doc. C1–2017–10818 Filed 6–29–17; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0969]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Roche Molecular Systems, Inc. for the *LightMix® Zika rRT–PCR Test.* FDA revoked this Authorization on March 13, 2017, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Roche Molecular Systems, Inc. by letter dated March 10, 2017. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of March 13, 2017.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 26, 2016, FDA issued an EUA to Roche Molecular Systems, Inc. for the *LightMix® Zika rRT–PCR Test,* subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on October 28, 2016 (81 FR 75092), as required by section 564(h)(1) of the FD&C Act. Under section 564(g)(2), the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no

longer met or other circumstances make such revocation appropriate to protect the public health or safety.

II. EUA Revocation Request for an In Vitro Diagnostic Device for Detection of the Zika Virus

On March 10, 2017, Roche Molecular Systems, Inc. requested, and on March 13, 2017, FDA revoked, the EUA for the *LightMix® Zika rRT–PCR* Test because the criteria for issuance were no longer met and other circumstances made such revocation appropriate to protect the public health or safety.

II. Electronic Access

An electronic version of this document and the full text of the revocation are available on the Internet at *https://www.regulations.gov.*

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Roche Molecular Systems, Inc.'s *LightMix® Zika rRT–PCR Test.* The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 13, 2017

Angela Tucker, Ph.D.
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Dear Dr. Tucker:

This letter is in response to your request dated March 10, 2017, that the Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA160017) for emergency use of Roche Molecular Systems, Inc.'s ("Roche") *LightMix® Zika rRT-PCR Test* issued on August 26, 2016, and amended on November 23, 2016. Roche has decided to no longer market the product.

Under section 564(g)(2) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 360bbb-3(g)(2), FDA has determined that the criteria for authorization under section 564(c) of the Act are no longer met. The known and potential benefits of the test for detecting Zika virus and diagnosing Zika virus infection no longer outweigh the known and potential risk of the product due to concerns regarding the false positive results observed. In addition, the product will no longer be marketed and these circumstances make revocation appropriate to protect the public health or safety.

Accordingly, FDA revokes the EUA for emergency use of the *LightMix® Zika rRT-PCR Test*, under section 564(g) of the Act. As of the date of this letter, the *LightMix® Zika rRT-PCR Test* that was authorized by FDA for use by clinical laboratories for the qualitative detection of RNA from Zika virus is no longer authorized by FDA.

FDA encourages Roche to instruct laboratories to discontinue use of and discard any remaining inventory immediately.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564 of the Act, 21 U.S.C. 360bbb-3.

Sincerely,

Stephen Ostroff, M.D.
Acting Commissioner of Food and Drugs

Dated: June 21, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13666 Filed 6–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1486]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for in vitro diagnostic devices for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Nanobiosym Diagnostics, Inc. and DiaSorin Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Nanobiosym Diagnostics, Inc. is effective as of March 20, 2017; the Authorization for DiaSorin Inc. is effective as of April 5, 2017.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product

intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA[1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

II. EUA Requests for In Vitro Diagnostic Devices for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On February 24, 2017, Nanobiosym Diagnostics, Inc. requested, and on March 20, 2017, FDA issued, an EUA for the Gene-RADAR® Zika Virus Test, subject to the terms of the Authorization. On March 30, 2017, DiaSorin Inc. requested, and on April 5, 2017, FDA issued an EUA for the LIAISON® XL Zika Capture IgM Assay, subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *https://www.regulations.gov/.*

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of two in vitro diagnostic devices for detection of Zika virus subject to the terms of the Authorizations. The Authorizations in their entirety (not including the authorized versions of the fact sheets and other written materials) follow and provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 20, 2017

Anita Goel, MD, Ph.D.
Chairman and CEO
Nanobiosym Diagnostics, Inc.
245 First Street, 18th Floor
Cambridge, MA 02142

Dear Dr. Goel:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Nanobiosym Diagnostics, Inc.'s ("Nanobiosym") Gene-RADAR® Zika Virus Test for the qualitative detection of RNA from Zika virus in human serum from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in serum during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum, following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."

[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on November 16, 2016).

[3] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Gene-RADAR® Zika Virus Test (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Gene-RADAR® Zika Virus Test for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Gene-RADAR® Zika Virus Test, when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Gene-RADAR® Zika Virus Test for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Gene-RADAR® Zika Virus Test for detecting Zika virus and diagnosing Zika virus infection.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Gene-RADAR® Zika Virus Test by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or

[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

The Authorized Gene-RADAR® Zika Virus Test

The Gene-RADAR® Zika Virus Test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum and other authorized specimen types.

To perform the Gene-RADAR® Zika Virus Test, the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the Gene-RADAR® Platform, or other authorized instruments.

The Gene-RADAR® Zika Virus Test includes the following materials or other authorized materials: Gene-RADAR® Zika Virus Kit Buffer 1 (containing primers, probes and reaction buffer), Gene-RADAR® Zika Virus Internal Process Control, Gene-RADAR® Zika Virus Positive/Negative Control, Gene-RADAR® Nanochips for use with samples and controls. The Gene-RADAR® Zika Virus Test also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized Gene-RADAR® Zika Virus Test Instructions for Use.

The Gene-RADAR® Zika Virus Test requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Gene-RADAR® Zika Virus Test Instructions for Use:

- Gene-RADAR® Zika Virus Positive Control: Synthetic Zika RNA target sequence that can be amplified and detected – run with each batch of patient specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- Negative Control: DNase and RNase-free water – run with each batch of patient specimens. Monitors for reagent and system contamination.
- Gene-RADAR® Zika Virus Internal Process Control: inactivated and stabilized MS2 Bacteriophage, requires extraction – added to each sample and control during the extraction step. The MS2 RNA is co-extracted and co-amplified with the target nucleic acid, and monitors for integrity of the kit reagents, equipment function and the presence of amplification inhibitors in the samples.

The above described Gene-RADAR® Zika Virus Test, when labeled consistently with the labeling authorized by FDA entitled "Gene-RADAR® Zika Virus Test Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Nanobiosym in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Gene-RADAR® Zika Virus Test is authorized to be accompanied by the

following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Gene-RADAR® Zika Virus Test Results
- Fact Sheet for Patients: Understanding Results from the Gene-RADAR® Zika Virus Test

As described in Section IV below, Nanobiosym and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized Gene-RADAR® Zika Virus Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Gene-RADAR® Zika Virus Test in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Gene-RADAR® Zika Virus Test may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized Gene-RADAR® Zika Virus Test, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Gene-RADAR® Zika Virus Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Gene-RADAR® Zika Virus Test described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Gene-RADAR® Zika Virus Test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Gene-RADAR® Zika Virus Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Nanobiosym and Its Authorized Distributor(s)

A. Nanobiosym and its authorized distributor(s) will distribute the authorized Gene-RADAR® Zika Virus Test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Nanobiosym and its authorized distributor(s) will provide to authorized laboratories the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Patients.

C. Nanobiosym and its authorized distributor(s) will make available on their websites the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Patients.

D. Nanobiosym and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Nanobiosym and its authorized distributor(s) will ensure that the authorized laboratories using the authorized Gene-RADAR® Zika Virus Test have a process in place for reporting test results to healthcare providers and relevant public health

authorities, as appropriate.[6]

F. Through a process of inventory control, Nanobiosym and its authorized distributor(s) will maintain records of device usage.

G. Nanobiosym and its authorized distributor(s) will collect information on the performance of the test. Nanobiosym will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Nanobiosym becomes aware.

H. Nanobiosym and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Gene-RADAR® Zika Virus Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Nanobiosym Diagnostics, Inc.

I. Nanobiosym will notify FDA of any authorized distributor(s) of the Gene-RADAR® Zika Virus Test, including the name, address, and phone number of any authorized distributor(s).

J. Nanobiosym will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. Nanobiosym may request changes to the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR® Zika Virus Test Fact Sheet for Patients. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. Nanobiosym may request the addition of other instruments for use with the authorized Gene-RADAR® Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. Nanobiosym may request the addition of other extraction methods for use with the authorized Gene-RADAR® Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. Nanobiosym may request the addition of other specimen types for use with the authorized Gene-RADAR® Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

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[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Nanobiosym, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

O. Nanobiosym may request the addition and/or substitution of other control materials for use with the authorized Gene-RADAR® Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Nanobiosym may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Gene-RADAR® Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Nanobiosym will assess traceability[7] of the Gene-RADAR® Zika Virus Test with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Nanobiosym will update its labeling to reflect the additional testing.

R. Nanobiosym will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

S. Authorized laboratories will include with reports of the results of the Gene-RADAR® Zika Virus Test the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories will perform the Gene-RADAR® Zika Virus Test using the QIAamp® Viral RNA Mini Kit or with other authorized extraction methods.

U. Authorized laboratories will perform the Gene-RADAR® Zika Virus Test on the Gene-RADAR® Platform, or other authorized instruments.

V. Authorized laboratories will perform the Gene-RADAR® Zika Virus Test on human serum or other authorized specimen types.

W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

X. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (*via* email CDRH-EUA-Reporting@fda.hhs.gov) and Nanobiosym any suspected occurrence of false positive or false negative results of which they become aware.

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[7] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Nanobiosym, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

Y. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Nanobiosym, Its Authorized Distributor(s) and Authorized Laboratories

Z. Nanobiosym, its authorized distributor(s), and authorized laboratories, will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

AA. All advertising and promotional descriptive printed matter relating to the use of the authorized Gene-RADAR® Zika Virus Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized Gene-RADAR® Zika Virus Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Gene-RADAR® Zika Virus Test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Gene-RADAR® Zika Virus Test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Stephen Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 5, 2017

Mari Meyer
Vice President, Regulatory and Clinical Affairs, North America
DiaSorin Incorporated
1951 Northwestern Avenue
Stillwater, MN 55082

Dear Ms. Meyer:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of DiaSorin Incorporated's ("DiaSorin") LIAISON® XL Zika Capture IgM Assay for the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting the Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories,[1] pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Specimens used with the LIAISON® XL Zika Capture IgM Assay should be collected between 8 days and 10 weeks after onset of symptoms or risk of exposure. Where there are presumptive Zika IgM positive and presumptive recent Zika positive results from the LIAISON® XL Zika Capture IgM Assay, confirmation of the presence of anti-Zika IgM antibodies requires additional testing, as described in the Scope of Authorization of this letter (Section II) and in the authorized Instructions for Use document, and/or consideration alongside test results for other patient-matched specimens using the latest CDC testing algorithms for the diagnosis of Zika virus infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus.[2] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or

[1] For ease of reference, this letter will refer to "laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[3]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the LIAISON® XL Zika Capture IgM Assay (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the presumptive qualitative detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the LIAISON® XL Zika Capture IgM Assay for the presumptive qualitative detection of Zika virus IgM antibodies in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the LIAISON® XL Zika Capture IgM Assay may be effective in diagnosing recent Zika virus infection, and that the known and potential benefits of the LIAISON® XL Zika Capture IgM Assay for diagnosing Zika virus infection outweigh the known and potential risks of such product, when, for presumptive Zika IgM positive and presumptive recent Zika positive results, additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered; and

3. There is no adequate, approved, and available alternative to the emergency use of the LIAISON® XL Zika Capture IgM Assay for diagnosing Zika virus infection.[4]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized LIAISON® XL Zika Capture IgM Assay by authorized laboratories for the presumptive qualitative detection of Zika virus IgM antibodies in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other

[3] HHS. *Determination and Declaration Regarding Emergency Use of In Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection.* 81 Fed. Reg. 10878 (March 2, 2016).

[4] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

epidemiological criteria for which Zika virus testing may be indicated) when, for presumptive Zika IgM positive and presumptive recent Zika positive results, additional testing (as described in the Instructions for Use document) is performed[5] and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered.

The Authorized LIAISON® XL Zika Capture IgM Assay

The LIAISON® XL Zika Capture IgM Assay is an automated immunoassay utilizing chemiluminescent detection technology for the *in vitro* presumptive qualitative detection of Zika virus IgM antibodies in human sera and other authorized specimen types from individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). The test procedure is based on capturing human IgM and IgG antibodies from the patient specimen using magnetic particles functionalized with either anti-human-IgM antibody or anti-human-IgG antibody followed by the addition of Zika virus specific NS1 antigen and detector conjugate. The IgG result is used as an aid in the identification of a recent Zika viral infection when the IgM result falls in the dual cut-off zone as outlined in the LIAISON® XL Zika Capture IgM Assay Instructions for Use.

One of the limitations of this test is the possibility of false positive results in patients with a history of infection with other flaviviruses. For presumptive Zika IgM positive or presumptive recent Zika positive results, additional testing (as described in the Instructions for Use document) and/or consideration of test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, is therefore required to confirm Zika virus infection.

The automated assay uses two separate reagent packs (ZIKV-M and ZIKV-C Reagent Integrals) which contain magnetic beads coated with either a monoclonal anti-human-IgM antibody or a monoclonal anti-human-IgG antibody. Calibrators, patient sera or controls are then incubated with both reagent packs during the LIAISON® XL Zika Capture IgM Assay procedure and either human IgM antibodies or human IgG antibodies are captured by the appropriate magnetic particles. Following a wash cycle, the magnetic particles are then incubated with a recombinant Zika virus NS1 antigen-isoluminol conjugate, washed and reagents added to induce chemiluminescence that can be measured by the LIAISON® XL Analyzer or other instruments that may be authorized. The LIAISON® XL Zika Capture IgM Assay requires both the ZIKV-M and ZIKV-C Reagent Integrals to be calibrated under specific conditions described in the authorized LIAISON® XL Zika Capture IgM Assay Instructions for Use.

The LIAISON® XL Zika Capture IgM Assay includes the following materials, or other authorized materials:

- **ZIKV-M Reagent Integral:**

[5] As discussed in the Instructions for Use document, the additional testing for presumptive Zika IgM positive or presumptive recent Zika positive results is to be performed using the latest CDC testing algorithms for the diagnosis of Zika virus infection.

- Magnetic Particles – coated with a mouse monoclonal antibody to human IgM
- Calibrator 1 - Human serum/defibrinated plasma containing Zika virus IgM
- Calibrator 2 - Human serum/defibrinated plasma containing Zika virus IgM
- Specimen Diluent
- Assay Buffer

- **ZIKV-C Reagent Integral:**
  - Magnetic Particles – coated with a mouse monoclonal antibody to human IgG
  - Specimen Diluent
  - Assay Buffer

- **Additional components not on the Reagent Integrals:**
  - ZIKV-M Conjugate Lyophilized – recombinant Zika virus NS1 antigen conjugated to an isoluminol derivative
  - ZIKV-C Conjugate Lyophilized – recombinant Zika virus NS1 antigen conjugated to an isoluminol derivative
  - ZIKV-C Calibrator 1- Human serum/defibrinated plasma containing Zika virus IgG
  - ZIKV-C Calibrator 2- Human serum/defibrinated plasma containing Zika virus IgG

The LIAISON® XL Zika Capture IgM Assay requires the following control materials or other authorized control materials, which are not provided with the test:

- **LIAISON® XL Zika Capture IgM Control Set:** The positive control aids in verifying the validity of the kit.

Controls listed above must be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. Controls must generate expected results in order for patient results to be considered valid.

The LIAISON® XL Zika Capture IgM Assay also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized LIAISON® XL Zika Capture IgM Assay Instructions for Use.

The above described LIAISON® XL Zika Capture IgM Assay, when labeled consistently with the labeling authorized by FDA entitled "LIAISON® XL Zika Capture IgM Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law. This labeling may be revised by DiaSorin in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH).

The above described LIAISON® XL Zika Capture IgM Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpreting LIAISON® XL Zika Capture IgM Assay Results
- Fact Sheet for Patients: Understanding Results from the LIAISON® XL Zika Capture IgM Assay

Other Fact Sheets developed by DiaSorin in consultation with, and with concurrence of, the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OIR/CDRH may be authorized to accompany the above described LIAISON® XL Zika Capture IgM Assay and to be made available to healthcare providers and patients.

As described in Section IV below, DiaSorin is also authorized to make available additional information relating to the emergency use of the authorized LIAISON® XL Zika Capture IgM Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized LIAISON® XL Zika Capture IgM Assay in the specified population, when used for presumptive qualitative detection of Zika virus IgM antibodies and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized LIAISON® XL Zika Capture IgM Assay may be effective in the diagnosis of recent Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized LIAISON® XL Zika Capture IgM Assay, when used to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized LIAISON® XL Zika Capture IgM Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the LIAISON® XL Zika Capture IgM Assay described above is authorized to diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the LIAISON® XL Zika Capture IgM Assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the LIAISON® XL Zika Capture IgM Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

DiaSorin and Its Authorized Distributor(s)

A. DiaSorin and its authorized distributor(s) will distribute the authorized LIAISON® XL Zika Capture IgM Assay with the authorized labeling only to authorized laboratories. DiaSorin may request changes to the authorized labeling. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. DiaSorin and its authorized distributor(s) will provide to authorized laboratories the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Healthcare Providers and the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Patients, and any additional LIAISON® XL Zika Capture IgM Assay Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.

C. DiaSorin and its authorized distributor(s) will make available on their websites the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Healthcare Providers and the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Patients, and any additional LIAISON® XL Zika Capture IgM Assay Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.

D. DiaSorin and its authorized distributor(s) will inform authorized laboratories and relevant

public health authority(ies) of this EUA, including the terms and conditions herein.

E. DiaSorin and its authorized distributor(s) will ensure that authorized laboratories using the authorized LIAISON® XL Zika Capture IgM Assay have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

F. Through a process of inventory control, DiaSorin and its authorized distributor(s) will maintain records of device usage.

G. DiaSorin and its authorized distributor(s) will collect information on the performance of the assay. DiaSorin will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the assay of which DiaSorin becomes aware.

H. DiaSorin and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized LIAISON® XL Zika Capture IgM Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

DiaSorin

I. DiaSorin will notify FDA of any authorized distributor(s) of the LIAISON® XL Zika Capture IgM Assay, including the name, address, and phone number of any authorized distributor(s).

J. DiaSorin will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. DiaSorin may request changes to the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Healthcare Providers and the authorized LIAISON® XL Zika Capture IgM Assay Fact Sheet for Patients. DiaSorin may also develop new LIAISON® XL Zika Capture IgM Assay Fact Sheets for Healthcare Providers and Patients, if appropriate, and may request changes to such Fact Sheets. All such requests listed in this condition of authorization will be made by DiaSorin in consultation with, and require concurrence of, OCET/OCS/OC and DMD/OIR/CDRH.

L. DiaSorin may request the addition of other instruments for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. DiaSorin may request the addition of other ancillary reagents for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in

[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that DiaSorin and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition (see http://www.cdc.gov/zika/).

consultation with, and require concurrence of, DMD/OIR/CDRH.

N. DiaSorin may request the addition of other specimen types for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. DiaSorin may request the addition of other control materials for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. DiaSorin may request substitution for or changes to the authorized materials used in the detection process of the human anti-Zika IgM and human anti-Zika IgG in the specimen. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. DiaSorin will track adverse events and report to FDA under 21 CFR Part 803.

R. DiaSorin will evaluate the performance of the LIAISON® XL Zika Capture IgM Assay with any FDA-recommended or established panel(s) of characterized clinical specimens, and will submit that performance data to FDA. After DMD/OIR/CDRH's review of and concurrence with the data, DiaSorin will update its labeling, in consultation with, and with concurrence of, DMD/OIR/CDRH, to reflect the additional testing.

S. DiaSorin will assess traceability[7] of the LIAISON® XL Zika Capture IgM Assay with any FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, DiaSorin will update its labeling to reflect the additional testing.

T. DiaSorin will track the performance of the LIAISON® XL Zika Capture IgM Assay and report to DMD/OIR/CDRH on a semi-annual basis.

Authorized Laboratories

U. Authorized laboratories will include with reports of the results of the LIAISON® XL Zika Capture IgM Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients, and any additional LIAISON® XL Zika Capture IgM Assay Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

V. Authorized laboratories will perform the LIAISON® XL Zika Capture IgM Assay on serum or with other authorized specimen types.

W. Authorized laboratories will perform the LIAISON® XL Zika Capture IgM Assay on the LIAISON® XL Analyzer or on other authorized instruments.

[7] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

X. Within the United States and its territories, authorized laboratories will report all presumptive Zika IgM positive and presumptive recent Zika positive results to DiaSorin.

Y. Authorized laboratories will have a process in place to assure that, for presumptive Zika IgM positive and presumptive recent Zika positive results, additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, are considered.

Z. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

AA. Authorized laboratories will collect information on the performance of the assay and report to DMD/OIR/CDRH (*via* email CDRH-EUA-Reporting@fda.hhs.gov) and DiaSorin any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.

BB. All laboratory personnel using the assay must be appropriately trained in performing and interpreting immunoassay techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the algorithm used for the interpretation of results of the LIAISON® XL Zika Capture IgM Assay.

DiaSorin, Its Authorized Distributor(s), and Authorized Laboratories

CC. DiaSorin, its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

DD. All advertising and promotional descriptive printed matter relating to the use of the authorized LIAISON® XL Zika Capture IgM Assay shall be consistent with the authorized Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

EE. All advertising and promotional descriptive printed matter relating to the use of the authorized LIAISON® XL Zika Capture IgM Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that DiaSorin and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition (see http://www.cdc.gov/zika/).

Page 10 – Ms. Meyer, DiaSorin Inc.

- This test has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized LIAISON® XL Zika Capture IgM Assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized LIAISON® XL Zika Capture IgM Assay as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: June 26, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13720 Filed 6–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research (R21).

Date: July 17, 2017.

Time: 1:00 p.m. 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892, 301–827–5833, *ivan.navarro@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; SEP II: Multi-site Clinical Trials.

Date: July 27, 2017.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 26, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13696 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: September 7, 2017.

Open: September 7, 2017, 8:00 a.m. to 3:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Research; and Administrative and Program Developments.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892.

Closed: September 7, 2017, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892.

Contact Person: Robert Finkelstein, Ph.D., Director, Division of Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Bethesda, MD 20892, (301) 496–9248.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.ninds.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 26, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13698 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01) & NIAID Resource-Related Research Projects (R24).

Date: July 24–25, 2017.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4H200, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Nancy Vazquez-Maldonado, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F52B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5044, *nvazquez@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 26, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13695 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 16–071: Behavioral Science Track Awards for Rapid Transition (B/START).

Date: July 18, 2017.

Time: 1:30 p.m. to 3:00 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: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biobehavioral Applications in Ethology and Substance Abuse.

Date: July 20–21, 2017.

Time: 11:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Andrea B Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, (301) 455–1761, *kellya2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vascular Biology and Hematology.

Date: July 27, 2017.

Time: 1:15 p.m. to 3:30 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: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition, and Reproductive Science.

Date: July 31, 2017.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182 MSC 7892, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 26, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13692 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Regulatory Affairs Support (8933).

Date: July 27, 2017.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5702 *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 26, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13697 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee, CIDR Member Conflict,

Date: July 21, 2017.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Suite 3051, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rudy Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Bethesda, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 26, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13694 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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; Cellular Aspects of Metabolism.

Date: July 11, 2017.

Time: 1:00 p.m. to 3:00 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: Antonello Pileggi, Ph.D., MD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, Bethesda, MD 20892–7892, (301) 402–6297, *pileggia@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurogenesis and Cell Fate MAKE-UP.

Date: July 11–12, 2017.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892 (301) 435–1178, *fujiij@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 26, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–13693 Filed 6–29–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration, (SAMHSA) Center for Mental Health Services (CMHS) National Advisory Council (NAC) will meet on July 27, 2017, from 3:00 p.m. to 4:00 p.m. (EDT) in a closed teleconference meeting.

The meeting will include discussion and evaluation of grant applications reviewed by SAMHSA's Initial Review Groups, and involves an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, the meeting will be closed to the public as determined by the Acting Deputy Assistant Secretary for Mental Health and Substance Use, in accordance with Title 5 U.S.C. 552b(c)(4) and (6) and Title 5 U.S.C. App. 2, 10(d).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council Web site at *http://www.samhsa.gov/about-us/advisory-councils/cmhs-national-advisory-council* or by contacting Ms. Pamela Foote (see contact information below).

Committee Name: Substance Abuse and Mental Health Services Administration; Center for Mental Health Services National Advisory Council.

Dates/Time/Type: Thursday, July 27, 2017, 3:00 p.m. to 4:00 p.m. EDT: CLOSED.

Place: SAMHSA, 5600 Fishers Lane, 14th Floor, Conference Room 14SEH02, Rockville, Maryland 20857.

Contact: Pamela Foote, Designated Federal Official, SAMHSA CMHS NAC, 5600 Fishers Lane, Room 14E53C, Rockville, Maryland 20857, Telephone: (240) 276–1279, *Fax:* (301) 480–8491, *Email: pamela.foote@samhsa.hhs.gov.*

Carlos Castillo,

SAMHSA, Committee Management Officer.

[FR Doc. 2017–13734 Filed 6–29–17; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–0316]

National Boating Safety Advisory Council; Vacancies

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the National Boating Safety Advisory Council. This Council advises the Coast Guard on recreational boating safety regulations and other major boating safety matters.

DATES: Completed applications should reach the Coast Guard on or before August 29, 2017.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the National Boating Safety Advisory Council and specifying which membership category the applicant is applying under, along with a resume detailing the applicant's boating experience via one of the following methods:

- By email: *NBSAC@uscg.mil* (preferred).
- By mail: Commandant (CG–BSX–2)/NBSAC, *Attn:* Mr. Jeff Ludwig, U.S. Coast Guard, 2703 Martin Luther King Ave. SE., Stop 7501, Washington, DC 20593–7501.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Ludwig, Alternate Designated Federal Officer of the National Boating Safety Advisory Council; telephone 202–372–1061 or email at *NBSAC@uscg.mil.*

SUPPLEMENTARY INFORMATION: The National Boating Safety Advisory Council is a Federal advisory committee which operates under the provisions of Federal Advisory Committee Act, (Title 5 U.S.C., Appendix). It was established under the authority of 46 United States Code 13110 and advises the Coast Guard on boating safety regulations and other major boating safety matters. The Council usually meets at least twice each year at a location selected by the Coast Guard. It may also meet for extraordinary purposes. Subcommittees or working groups may also meet to consider specific issues.

Each member serves for a term of three years. Members may be considered to serve a maximum of two consecutive full terms. All members serve at their own expense and receive no salary, or other compensation from the Federal Government. The exception to this policy is when attending National Boating Safety Advisory Council meetings; members may be reimbursed for travel expenses and provided per diem in accordance with Federal Travel Regulations.

We will consider applications for the following seven positions that will be vacant on January 1, 2018:

- Three representatives of State officials responsible for State boating safety programs;
- Two representatives of recreational boat and associated equipment manufacturers; and
- Two representatives of national recreational boating organizations or the general public.

If you are selected as a member from the general public, you will be appointed and serve as a Special Government Employee as defined in section 202(a) of Title 18, United States Code. Applicants for appointment as a Special Government Employee, applicants are required to complete a Confidential Financial Disclosure Report (OGE Form 450). The Coast Guard may not release the reports or the information in them to the public except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Only the Designated Coast Guard Ethics Official or his or her designee may release a Confidential Financial Disclosure Report. Applicants can obtain this form by going to the Web site of the Office of Government Ethics (*www.oge.gov*) or by contacting the individual listed above in **FOR FURTHER INFORMATION CONTACT**. Applications for a member drawn from the general public that are not accompanied by a completed OGE Form 450 will not be considered.

Registered lobbyists are not eligible to serve on federal advisory committees in an individual capacity. See ''Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards and Commissions'' (79 FR 47482, August 13, 2014). The position we list for a member from the general public would be someone appointed in their capacity and would be designated as a Special Government Employee as defined in section 202(a) of Title 18, U.S.C. Registered lobbyists are lobbyist as defined in 2 U.S.C. 1602 who are required by 2 U.S.C. 1603 to register

with the Secretary of the Senate and the Clerk of the House of Representatives.

Applicants are considered for membership on the basis of their particular expertise, knowledge, and experience in recreational boating safety. In addition to recreational boating safety experience, the Coast Guard is particularly interested in applicants who also have experience developing and implementing national media outreach campaigns designed to influence the decision-making of targeted audiences. The vacancies announced in this notice apply to membership positions that become vacant on January 1, 2018. Appointments for the 2017 vacancies remain pending, and applications received in response to this notice may also be used to fill the seven positions which became vacant on January 1, 2017. Applicants for the 2017 vacancies announced in the **Federal Register** on March 22, 2016, (81 FR 15326) will automatically be considered for the 2018 vacancies and do not need to submit another application. Individuals, who submitted an application for any year prior to 2017, are asked to re-submit an application if the individual wishes to apply for any of the vacancies announced in this notice.

To be eligible, applicants should have experience in one of the categories listed in the **SUPPLEMENTARY INFORMATION** section.

The Department of Homeland Security does not discriminate in selection of Council members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability and genetic information, age, membership in an employee organization, or other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

If you are interested in applying to become a member of the Council, send your cover letter and resume to Mr. Jeff Ludwig, Alternate Designated Federal Officer of the National Boating Safety Advisory Council via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

J.F. Williams,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2017–13754 Filed 6–29–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Delay of Effective Date for the Automated Commercial Environment (ACE) Becoming the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Drawback and Duty Deferral Entry and Entry Summary Filings

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Delay of effective date.

SUMMARY: On August 30, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** announcing plans to make the Automated Commercial Environment (ACE) the sole electronic data interchange (EDI) system authorized by the Commissioner of CBP for processing electronic drawback and duty deferral entry and entry summary filings. This notice announces that the effective date for that transition has been delayed until further notice.

DATES: *The effective date is delayed until further notice.* CBP will publish a subsequent notice announcing the date when ACE will become the sole CBP-authorized EDI system for processing electronic drawback and duty deferral entry and entry summary filings, and ACS will no longer be a CBP-authorized EDI system for purposes of processing these filings.

FOR FURTHER INFORMATION CONTACT: Questions related to this notice may be emailed to *ASKACE@cbp.dhs.gov* with the subject line identifier reading ''ACS to ACE Drawback and Duty Deferral Entry and Entry Summary Filings transition.''

SUPPLEMENTARY INFORMATION: On August 30, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** (81 FR 59644) announcing plans to make the Automated Commercial Environment (ACE) the sole electronic data interchange (EDI) system authorized by the Commissioner of CBP for processing electronic drawback and duty deferral entry and entry summary filings, with an effective date of October 1, 2016. The document also announced that the Automated Commercial System (ACS) would no longer be a CBP-authorized EDI system for purposes of processing these electronic filings. Finally, the notice announced a name change for the ACE filing code for duty deferral and the creation of a new ACE filing code for all electronic drawback filings, replacing the six distinct drawback codes previously filed in ACS. The effective date for these changes was subsequently delayed. On June 8, 2017, CBP published a notice in the **Federal Register** (82 FR 26698) announcing that the changes announced in the August 30, 2016 **Federal Register** notice would become effective on July 8, 2017.

This notice announces that the effective date announced in the June 8, 2017 **Federal Register** notice is delayed until further notice. CBP will publish a subsequent notice announcing the effective date for these changes.

Dated: June 26, 2017.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2017–13827 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Delayed Effective Date for Modifications of the National Customs Automation Program Tests Regarding Reconciliation, Post-Summary Corrections, and Periodic Monthly Statements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Delay of effective date.

SUMMARY: This notice announces that the effective date for the modifications to the National Customs Automation Program (NCAP) tests regarding Reconciliation, Post-Summary Corrections (PSC), and Periodic Monthly Statements (PMS) is delayed until further notice. U.S. Customs and Border Protection (CBP) announced these modifications in notices previously published in the **Federal Register**.

DATES: The effective date for the modifications to the reconciliation, PSC, and PMS NCAP tests is delayed until further notice. CBP will publish a notice in the **Federal Register** announcing a new effective date for changes to these NCAP tests.

ADDRESSES: Comments concerning the reconciliation test program may be submitted at any time during the test via email, with a subject line identifier reading, ''Comment on Reconciliation test'', to *OFO-RECONFOLDER@cbp.dhs.gov.*

Comments concerning the PSC and PMS test programs may be submitted

via email to Monica Crockett at *ESARinfoinbox@dhs.gov* with a subject line identifier reading, ''Post-Summary Corrections and Periodic Monthly Statements.''

FOR FURTHER INFORMATION CONTACT:

Reconciliation: Acenitha Kennedy, Entry Summary and Revenue Branch, Trade Policy and Programs, Office of Trade at (202) 863–6064 or *ACENITHA.KENNEDY@CBP.DHS.GOV.*

PSC and PMS: For policy-related questions, contact Randy Mitchell, Director, Commercial Operations, Trade Policy and Programs, Office of Trade, at *Randy.Mitchell@cbp.dhs.gov.* For technical questions related to ABI transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Representative Branch at (703) 650–3500.

SUPPLEMENTARY INFORMATION:

Background

I. Reconciliation Test

On December 12, 2016, U.S. Customs and Border Protection (CBP) published a notice entitled ''Modification of the National Customs Automation Program Test Regarding Reconciliation and Transition of the Test from the Automated Commercial System to the Automated Commercial Environment'' in the **Federal Register** (81 FR 89486), with an effective date of January 14, 2017. This notice announced modifications to the National Customs Automation Program (NCAP) test regarding reconciliation, and the transition of the test from the Automated Commercial System (ACS) to the Automated Commercial Environment (ACE). The effective date for these changes was subsequently delayed. On June 8, 2017, CBP published a notice in the **Federal Register** (82 FR 26699) announcing that the effective date for the test modifications would be July 8, 2017.

This notice announces that the effective date for the modifications to the reconciliation test and for mandatory filing of reconciliation entries in ACE has been delayed until further notice.

II. Post-Summary Correction and Periodic Monthly Statement Tests

On December 12, 2016, CBP published a notice in the **Federal Register** (81 FR 89482) announcing plans to modify and clarify, effective January 14, 2017, the NCAP test regarding Post-Summary Correction (PSC) claims, and the NCAP test regarding Periodic Monthly Statements (PMS). Subsequently, on January 9, 2017, CBP published a second notice in the **Federal Register** (82 FR 2385), superseding the original notice. This notice announced CBP's plans to modify the PMS test and to modify and clarify the NCAP test regarding PSC claims to entry summaries that are filed in ACE. The effective date for these changes was subsequently delayed. On June 8, 2017, CBP published a notice in the **Federal Register** (82 FR 26699), announcing that the effective date for the modifications to the PSC and PMS tests would be July 8, 2017.

This notice announces that the effective date for the modifications to the PSC and PMS tests has been delayed until further notice.

Dated: June 26, 2017.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2017–13825 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4319–DR; Docket ID FEMA–2017–0001]

Kansas; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA–4319–DR), dated June 16, 2017, and related determinations.

DATES: *Effective Date:* June 23, 2017.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Kansas is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 16, 2017.

Stanton County for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Robert J. Fenton,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2017–13840 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2017–0026; OMB No. 1660–NW103]

Agency Information Collection Activities; Proposed Information Collection; Comment Request; Federal Emergency Management Agency Programs Customer Satisfaction Surveys

AGENCY: Federal Emergency Management Agency (FEMA), DHS.

ACTION: Notice of new information collection; request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a new information collection to replace a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of Individual Assistance customer satisfaction survey responses and information for assessment and improvement of the delivery of disaster assistance to individuals and households.

DATES: Comments must be submitted on or before August 29, 2017.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID

FEMA–2017–0026. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., Room 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jessica Guillory, Statistician, Customer Survey & Analysis Section, Recovery Directorate, FEMA at *Jessica.Guillory@fema.dhs.gov,* 940–891–8528. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This collection is in accordance with Executive Orders 12862 and 13571 requiring all Federal agencies to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. The Government Performance and Results Act (GPRA) (Pub. L. 103–62, 107 Stat. 285) requires agencies to set missions and goals and measure performance against them. In addition, the GPRA Modernization Act of 2010 (Pub. L. 111–352, 124 Stat. 3866) requires quarterly performance assessments of government programs for the purposes of assessing agency performance and improvement. FEMA will fulfill these requirements by collecting customer satisfaction program information through surveys of the Recovery Directorate's external customers.

Collection of Information

Title: Federal Emergency Management Agency Programs Customer Satisfaction Surveys.

Type of Information Collection: New information collection.

OMB Number: 1660–NW103.

FEMA Forms: FEMA Form 519–0–45, Preparedness Survey—Electronic; FEMA Form 519–0–44, Preparedness Survey—Phone; FEMA Form 519–0–47, Transitional Sheltering Assistance (TSA) Survey—Electronic; FEMA Form 519–0–46, Transitional Sheltering Assistance (TSA) Survey—Phone; FEMA Form 519–0–49, Temporary Housing Units (THU) Survey—Electronic; FEMA Form 519–0–48, Temporary Housing Units (THU) Survey—Phone; FEMA Form 519–0–51, Shelter and Temporary Essential Power (STEP) Survey—Electronic; FEMA Form 519–0–50, Shelter and Temporary Essential Power (STEP) Survey—Phone.

Abstract. Federal agencies are required to survey their customers to determine the kind and quality of services customers want and their level of satisfaction with those services. Analysis from the survey is used to measure FEMA's survivor-centric mission of being accessible, simple, timely and effective in meeting the needs of survivors.

Affected Public: Individuals and households.

Number of Respondents: 8,896.

Number of Responses: 8,896.

Estimated Total Annual Burden Hours: 5,548.

Estimated Cost: The estimated annual burden hour cost to respondents is $193,292. The estimated annual non-labor cost to respondents participating and traveling to focus groups is $30,816. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $716,338.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: June 26, 2017.

Tammi Hines,

Records Management Program Chief (Acting), Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2017–13699 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0038]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition To Remove the Conditions on Residence

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2017.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0038 in the body of the letter, the agency name and Docket ID USCIS–2009–0008. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0008;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW.,

Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0008 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition To Remove the Conditions on Residence.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–751; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households. This form is used by USCIS to verify the petitioner's status and determine whether they are eligible to have the conditions on their permanent resident status removed.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–751 is 159,119 and the estimated hour burden per response is 3.75 hours. The estimated total number of respondents for biometric processing is 318,238 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 969,035 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $19,492,200.

Dated: June 26, 2017.

Jerry Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2017–13724 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0075]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Affidavit of Support Under Section 213A of the Act, Form I–864; Contract Between Sponsor and Household Member, Form I–864A; EZ Affidavit of Support Under Section 213 of the Act, I–864EZ; Intending Immigrant's Affidavit of Support Exemption, I–864W

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 31, 2017. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *dhsdeskofficer@omb.eop.gov.* All submissions received must include the agency name and the OMB Control Number 1615–0075 in the subject line.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact

information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on March 8, 2017, at 82 FR 13650, allowing for a 60-day public comment period. USCIS did receive comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0029 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Affidavit of Support Under Section 213A of the Act; Contract Between Sponsor and Household Member; EZ Affidavit of Support under Section 213 of the Act; Intending Immigrant's Affidavit of Support Exemption.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–864, Form I–864A, Form I–864EZ, and Form I–864W; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households; USCIS uses the data collected on Form I–864 to determine whether the sponsor has the ability to support the sponsored alien under section 213A of the Immigration and Nationality Act. This form standardizes evaluation of a sponsor's ability to support the sponsored alien and ensures that basic information required to assess eligibility is provided by petitioners.

Form I–864A is a contract between the sponsor and the sponsor's household members. It is only required if the sponsor used the income of his or her household members to reach the required 125 percent of the Federal poverty guidelines. The contract holds these household members jointly and severally liable for the support of the sponsored immigrant. The information collection required on Form I–864A is necessary for public benefit agencies to enforce the Affidavit of Support in the event the sponsor used income of his or her household members to reach the required income level and the public benefit agencies are requesting reimbursement from the sponsor.

USCIS uses Form I–864EZ in exactly the same way as Form I–864; however, less information is collected from the sponsors as less information is needed from those who qualify in order to make a thorough adjudication.

USCIS uses Form I–864W to determine whether the intending immigrant meets the criteria for exemption of section 213A requirements. This form collects the immigrant's basic information, such as name and address, the reason for the exemption, and accompanying documentation in support of the immigrant's claim that they are not subject to section 213A.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for Form I–864 is 446,313 and the estimated hour burden per response is 6 hours; the estimated total number of respondents for Form I–864A is 42,892 and the estimated hour burden per response is 1.75 hours; the estimated total number of respondents for Form I–864EZ is 114,860 and the estimated hour burden per response is 2.5 hours; the estimated total number of respondents for Form I–864W is 98,119 hours and the estimated hour burden per response is 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this information collection is 3,138,208 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this information collection is $161,526,540.

Dated: June 26, 2017.

Jerry Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2017–13717 Filed 6–29–17; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2017–N020; FXES111604C0000–178–FF04E00000]

Proposed Programmatic Candidate Conservation Agreement With Assurances for the Louisiana Pinesnake in Louisiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from the Louisiana Department of Wildlife and Fisheries for an enhancement of survival permit (permit) pursuant to the Endangered Species Act of 1973. The permit application includes a proposed programmatic candidate conservation agreement with assurances (CCAA) for the Louisiana pinesnake. The term of the agreement would be 99 years. If approved, the CCAA would allow the applicant to enter into conservation management agreements with eligible non-Federal landowners throughout Bienville, Beauregard, Jackson, Natchitoches, Rapides, Sabine, Vernon, Winn, Grant, and Allen Parishes, Louisiana, and to issue certificates of inclusion to enrollees. We invite public comments on these documents.

DATES: We must receive any written comments at our Regional Office (see **ADDRESSES**) on or before July 31, 2017.

ADDRESSES: To request further information, review documents, or submit written comments, please use the following methods and specify that your information request or comments are in reference to the ''Programmatic CCAA for the Louisiana Pinesnake.''

• *Internet:* Documents may be viewed and downloaded on the Internet at *http://www.fws.gov/southeast/candidaetconservation/examples.html*.

• *Email: michael_harris@fws.gov.* Include ''Programmatic CCAA for the Louisiana Pinesnake'' in the subject line. Please include your name and return address in your message. If you do not receive a confirmation from us that we have received your message, contact us directly at either telephone number listed under **FOR FURTHER INFORMATION CONTACT**.

• *U.S. Mail:* Mr. Michael Harris, At-Risk Species Coordinator, Fish and Wildlife Service, Southeast Regional Office, 1875 Century Boulevard, Atlanta, GA 30345, or Mr. Joseph Ranson, Field Supervisor, Fish and Wildlife Service, Louisiana Ecological Services Field Office, 646 Cajundome Boulevard, Suite 400, Lafayette, LA 70506.

• *In-Person Drop-off, Viewing, or Pickup:* Call 404–679–7066 to make an appointment (necessary for viewing or pick-up only) during regular business hours at the Fish and Wildlife Service's Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, GA 30345; or call 337–291–3112 to make an appointment at the Louisiana Ecological Services Field Office, Fish and Wildlife Service, 646 Cajundome Boulevard, Suite 400, Lafayette, LA 70506. Written comments can be dropped off during regular business hours at either address on or before the closing date of the public comment period (see **DATES**). Requests for any documents must be in writing.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Harris, At-Risk Species Coordinator, at the Regional Office (see **ADDRESSES**), telephone: 404–679–7066; or Mr. David Castellanos, Imperiled Species Biologist, at the Louisiana Field Office (see **ADDRESSES**), telephone: 337–291–3112.

SUPPLEMENTARY INFORMATION: We have received an application from the Louisiana Department of Wildlife and Fisheries for an enhancement of survival permit (permit) pursuant to the Endangered Species Act of 1973 (Act). The permit application includes a proposed programmatic candidate conservation agreement with assurances (CCAA) for the Louisiana pinesnake (*Pituophis ruthveni*). The term of the CCAA would be 99 years. If approved, the CCAA would allow the applicant to enter into conservation management agreements with eligible non-Federal landowners throughout Bienville, Beauregard, Jackson, Natchitoches, Rapides, Sabine, Vernon, Winn, Grant, and Allen Parishes, Louisiana, and to issue certificates of inclusion to enrollees. We invite public comments on these documents.

Candidate Conservation Agreements With Assurances

Under a CCAA, participating property owners voluntarily undertake management activities on their properties to enhance, restore, or maintain habitat benefiting species that may warrant listing under the Act. CCAAs encourage private and other non-Federal property owners to implement conservation efforts for candidate and at-risk species by assuring them that they will not be subjected to increased property use restrictions should the species become listed as ''threatened'' or ''endangered'' under the Act in the future. Application requirements and issuance criteria for CCAAs are found in 50 CFR 17.22(d) and 17.32(d).

Parties' Agreement

The CCAA describes conservation measures designed to protect and enhance habitat for the benefit of the Louisiana pinesnake (covered species) on private or non-Federal public lands enrolled under the agreement. Enrolled landowners who implement these measures would receive assurances against take liability if the covered species were to be federally listed in the future. Conservation land use practices would vary according to the needs of a particular enrolled landowner. Typical measures include the use of prescribed fire, thinning of forests, and restoration of open-canopied pine (including longleaf pine). The CCAA also contemplates that other conservation measures may be developed in the future.

We specifically request information, views, and opinions from the public via this notice on our proposed Federal action, including our determination that the CCAA, including its proposed conservation measures, would have minor or negligible effects on the covered species. Therefore, we have determined that the incidental take permit for this project is ''low effect'' and qualifies for categorical exclusion under the National Environmental Policy Act (NEPA), as provided by 43 CFR 46.205 and 43 CFR 46.210. A low-effect project involves (1) minor or negligible effects on federally listed or candidate species or their habitats, and (2) minor or negligible effects on other environmental values or resources. Further, we specifically solicit information regarding the adequacy of the CCAA per 50 CFR parts 13 and 17.

Public Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Covered Area

The CCAA covers eligible lands in Bienville, Beauregard, Jackson, Natchitoches, Rapides, Sabine, Vernon, Winn, Grant, and Allen Parishes, Louisiana.

Next Steps

We will evaluate the application for enhancement of survival permit through candidate conservation agreement with assurances, including the CCAA, and any comments we receive to determine whether the application meets the requirements of section 10(a)(1)(A) of the Act and of applicable implementing regulations. We will also evaluate whether the section 10(a)(1)(A) enhancement of survival permit would comply with section 7 of the Act by conducting an intra-Service section 7 consultation. If we determine that the requirements are met, we will issue a permit under section 10(a)(1)(A) of the Act to the applicant in accordance with the applicable regulatory requirements. We will not make our final decision until after the end of the 30-day comment period and will fully consider all comments received during the comment period.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: June 23, 2017.

Luis J. Santiago,

Acting Regional Director.

[FR Doc. 2017–13760 Filed 6–29–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2017–N046; FXES11130800000–178–FF08EVEN00]

Receipt of Application for Incidental Take Permit; Low-Effect Habitat Conservation Plan for the Curletti Farm Employee Housing Project, Santa Barbara County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from Betteravia Farms, LLC, for an incidental take permit under the Endangered Species Act of 1973, as amended. The permit would authorize take of the federally endangered California tiger salamander (Santa Barbara distinct population segment) incidental to otherwise lawful activities associated with the Curletti Farm Employee Housing Project Habitat Conservation Plan. We invite public comment.

DATES: Written comments should be received on or before July 31, 2017.

ADDRESSES: You may download a copy of the draft habitat conservation plan and draft low-effect screening form and environmental action statement on the internet at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail to our Ventura office, or by phone (see **FOR FURTHER INFORMATION CONTACT**). Please address written comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. You may alternatively send comments by facsimile to (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Rachel Henry, Fish and Wildlife Biologist, at the above address or by calling (805) 644–1766.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received an application from Betteravia Farms, LLC (applicant), for an incidental take permit under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.;* Act). The applicant has agreed to follow all of the conditions in the habitat conservation plan for the project. The permit would authorize take of the Santa Barbara distinct population segment of the federally endangered California tiger salamander (*Ambystoma californiense*) incidental to otherwise lawful activities associated with the Curletti Farm Employee Housing Project Habitat Conservation Plan (HCP). We invite public comment on the application, the draft habitat conservation plan, draft low-effect screening form, and environmental action statement.

Background

The Santa Barbara distinct population segment of the California tiger salamander was listed by the Service as endangered on January 19, 2000 (65 FR 3096). Section 9 of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations prohibit the ''take'' of fish or wildlife species listed as endangered or threatened. ''Take'' is defined under the Act to include the following activities: ''[T]o harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the Act, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the Act as take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are in the Code of Federal Regulations at 50 CFR 17.32 and 17.22, respectively. Under the Act, protections for federally listed plants differ from the protections afforded to federally listed animals. Issuance of an incidental take permit also must not jeopardize the existence of federally listed fish, wildlife, or plant species. All species included in the incidental take permit would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

The applicants have applied for a permit for incidental take of the California tiger salamander. The potential taking would occur as a result of activities associated with the construction of the farm labor camp in suitable habitat for the covered species.

Our Preliminary Determination

The Service has made a preliminary determination that issuance of the permit is neither a major Federal action that will significantly affect the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.;* NEPA), nor will it individually or cumulatively have more than a negligible effect on the species covered in the HCP. Therefore, the permit qualifies for a categorical exclusion under NEPA.

Public Comments

If you wish to comment on the permit application, plan, and associated documents, you may submit comments by any one of the methods in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: June 26, 2017.

Stephen P. Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2017–13770 Filed 6–29–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2017–N024; FXES11130900000C2–178–FF09E32000]

Endangered and Threatened Wildlife and Plants; 5-Year Status Reviews of 23 Southeastern 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 (Service), are initiating 5-year status reviews of 23 species under the Endangered Species Act of 1973, as amended (Act). We conduct these reviews to ensure that the classification of species as threatened or endangered on the Lists of Endangered and Threatened Wildlife and Plants is accurate. A 5-year review is an assessment of the best scientific and commercial data available at the time of the review. Therefore, we are requesting submission of information that has become available since the last review of each of these species.

DATES: To allow us adequate time to conduct these reviews, we must receive your comments or information on or before August 29, 2017. However, we

will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information and review information we receive on these species, see ''Request for New Information.''

FOR FURTHER INFORMATION CONTACT: For species-specific information, see ''Request for New Information.''

SUPPLEMENTARY INFORMATION:

Why do we conduct a 5-year review?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain lists of endangered and threatened wildlife and plant species in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 17.12 (for plants). Section 4(c)(2)(A) of the Act 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.

Species Under Review

This notice announces our active review of 22 species that are currently listed as endangered:

Fish and Wildlife

Florida panther (*Puma concolor coryi*)
Puerto Rican broad-winged hawk (*Buteo platypterus brunnescens*)
Puerto Rican nightjar (*Caprimulgus noctitherus*)
Cumberland darter (*Etheostoma susanae*)
Rush darter (*Etheostoma phytopilum*)
Vermilion darter (*Etheostoma chermocki*)
Pygmy madtom (*Noturus stanauli*)
Cumberland bean (*Villosa trabalis*)
Ring pink (*Obovaria retusa*)
Anthony's riversnail (*Athearnia anthonyi*)

Plants

Arabis perstellata (Braun's rock-cress)
Chamaesyce deltoidea spp. deltoidea (Deltoid spurge)
Clematis morefieldii (Morefield's leatherflower)
Conradina verticillata (Cumberland rosemary)
Galactia smallii (Small's milkpea)
Lyonia truncata var. proctorii (no common name)
Polygala smallii (Tiny polygala)
Pityopsis ruthii (Ruth's golden aster)
Sarracenia rubra ssp.alabamensis (Alabama canebrake pitcher plant)
Schwalbea americana (American chaffseed)
Vernonia proctorii (no common name)
Adiantum vivesii (no common name)

This notice also announces our active review of 1 species that is currently listed as threatened:

Fish and Wildlife

Ozark cavefish (*Troglichthys rosae*)

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 to benefit the species;

D. Threat status and trends (see five factors under heading ''How Do We Determine Whether a Species Is Endangered or Threatened?''); 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.

Definitions

A. *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate which interbreeds when mature.

B. *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range.

C. *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

How do we determine whether a species is endangered or threatened?

Section 4(a)(1) of the Act establishes that we determine whether a species is endangered or threatened based on one or more of the following five factors:

A. The present or threatened destruction, modification, or curtailment of its habitat or range;

B. Overutilization for commercial, recreational, scientific, or educational purposes;

C. Disease or predation;

D. The inadequacy of existing regulatory mechanisms; or

E. Other natural or manmade factors affecting its continued existence.

Request for New Information

To do any of the following, contact the person associated with the species you are interested in below:

A. To get more information on a species;

B. To submit information on a species; or

C. To review information we receive, which will be available for public inspection by appointment, during normal business hours, at the listed addresses.

Mammals

• Florida panther: South Florida Ecological Services Field Office, U.S. Fish and Wildlife Service, 12085 State Road 29 S, Immokalee, FL 34142; fax 772–562–4288. For information on these species, contact David Shindle at the ES Field Office (by phone at 239–657–8013, or by email at *david_shindle@fws.gov*).

Birds

• Puerto Rican broad-winged hawk and Puerto Rican nightjar: Caribbean Ecological Services Field Office, U.S. Fish and Wildlife Service, Road 301, Km. 5.1, P.O. Box 491, Boqueron, PR 00622; fax 787–851–7440. For information on these species, contact Jose Cruz-Burgos at the ES Field Office (by phone at 787–851–7297, ext.218 or by email at *jose_cruz-burgos@fws.gov*).

Fishes

• Ozark Cavefish: Arkansas Ecological Services Field Office, U.S. Fish and Wildlife Service, 110 South Amity Road, Suite 300, Conway, Arkansas 72032; fax 501–513–4480. For information on these species, contact Tommy Inebnit at the ES Field Office (by phone at 501–513–4483 or by email at *thomas_inebnit@fws.gov*).

• Cumberland darter: Kentucky Ecological Services Field Office, U.S. Fish and Wildlife Service, 330 West Broadway, Frankfort, Kentucky 40601 fax 502–695–1024. For information on these species, contact Dr. Michael Floyd at the ES Field Office (by phone at 502–695–0468 ext. 102 or by email at *mike_floyd@fws.gov*).

• Rush darter and Vermilion darter: Mississippi Ecological Services Field Office, U.S. Fish and Wildlife Service, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Jackson, MS 39213; fax 601–965–4340. For information on these species, contact Daniel Drennen at the ES Field Office

(by phone at 601–321–1127 or by email at *daniel_drennen@fws.gov*).

• Pygmy madtom: Tennessee Ecological Services Field Office, U.S. Fish and Wildlife Service, U.S. Fish and Wildlife Service, 446 Neal Street, Cookeville, TN 38501; fax 931–528–7075. For information on these species, contact Warren Stiles at the ES Field Office (by phone at 931–525–4977 or by email at *warren_stiles@fws.gov*).

Clams

• Cumberland bean and Ring pink: Kentucky Ecological Services Field Office (see contact information above). For information on these species, contact Leroy Koch at the ES Field Office (by phone at 502–695–0468 ext. 106 or by email at *leroy_koch@fws.gov.*

Snails

• Anthony's riversnail: Tennessee Ecological Services Field Office (see contact information above). For information on these species, contact Stephanie Chance at the ES Field Office (by phone at 931–528–6481 ext. 211 or by email at *stephanie_chance@fws.gov*).

Plants

• *Arabis perstellata* (Braun's rock-cress): Kentucky Ecological Services Field Office. For information on these species, contact Dr. Michael Floyd (see contact information above).

• *Chamaesyce deltoidea spp. deltoidea* (Deltoid spurge), *Galactia smallii* (Small's milkpea), and *Polygala smallii* (Tiny polygala): South Florida Ecological Services Field Office, U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, FL 32960; fax 772–562–4288. For information on these species, contact David Bender at the ES Field Office (by phone at 772–469–4294 or by email at *david_bender@fws.gov*).

• *Clematis morefieldii* (Morefield's leatherflower), *Conradina verticillata* (Cumberland rosemary), and *Pityopsis ruthii* (Ruth's golden aster): Tennessee Ecological Services Field Office (see contact information above). For information on these species, contact Geoff Call at the ES Field Office (by phone at 931–525–4983 or by email at *geoff_call@fws.gov*).

• *Lyonia truncata var. proctorii* (no common name), *Vernonia proctorii* (no common name), and *Adiantum vivesii* (no common name): Caribbean Ecological Services Field Office. For information on these species, contact Jose Cruz-Burgos (see contact information above).

• *Sarracenia rubra ssp. alabamensis* (Alabama canebrake pitcher plant): Mississippi Ecological Services Field Office (see contact information above). For information on these species, contact Scott Wiggers at the ES Field Office (by phone at 228–475–0765 or by email at *marion_wiggers@fws.gov*).

• *Schwalbea americana* (American chaffseed): South Carolina Ecological Services Field Office, U.S. Fish and Wildlife Service, 176 Croghan Spur Road, Suite 200, Charleston, SC 29412; fax 843–727–4218. For information on these species, contact April Punsalan at the ES Field Office (by phone at 843–727–4707 ext. 218 or by email at *april_punsalan@fws.gov*).

We request any new information concerning the status of any of these 23 species. See ''What Information Do We Consider In Our Review?'' heading for specific criteria. Information submitted should be supported by 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.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We publish this document under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: April 18, 2017.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2017–13758 Filed 6–29–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R2–ES–2017–0036; FXES11130200000–178–FF02ENEH00]

Endangered and Threatened Wildlife and Plants; Mexican Wolf Draft Recovery Plan, First Revision

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our Mexican Wolf (*Canis lupus baileyi*) Draft Recovery Plan, First Revision (draft recovery plan). The Mexican wolf is listed as endangered under the Endangered Species Act of 1973, as amended (Act), and is currently found in Arizona and New Mexico, in the United States, and in Chihuahua, Mexico. The draft recovery plan includes specific recovery criteria to be met to enable us to remove this species from the List of Endangered and Threatened Wildlife. The first Mexican wolf recovery plan was completed in 1982. We request review and comment on the revised plan from local, State, and Federal agencies; Tribes; and the public, in both the United States and Mexico. We will also accept any new information on the Mexican wolf's status throughout its range to assist in finalizing the recovery plan.

DATES: *Comment submission:* To ensure consideration, we must receive written comments on or before August 29, 2017. However, we will accept information about any species at any time.

Public meetings: We will hold information meetings to provide the public with information on the draft recovery plan. Written comments on the draft recovery plan may be submitted at these meetings (oral comments will not be recorded). The dates and times of these information meetings are as follows:

1. July 18, 2017 (6:00 p.m. to 9:00 p.m.): Flagstaff, Arizona.
2. July 19, 2017 (6:00 p.m. to 9:00 p.m.): Pinetop, Arizona.
3. July 20, 2017 (6:00 p.m. to 9:00 p.m.): Truth or Consequences, New Mexico.
4. July 22, 2017 (2:00 p.m. to 5:00 p.m.): Albuquerque, New Mexico.

ADDRESSES: *Document availability:* If you wish to review the draft recovery plan and related documents, you may obtain copies by any of the following methods:

Electronically: Go to *http://www.regulations.gov* and enter FWS–R2–ES–2017–0036.

U.S. mail: U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna Road NE., Albuquerque, NM 87113; or

Telephone: (505) 346–2525.

Comment submission: If you wish to comment on the draft recovery plan, you may submit your comments in writing by either of the following methods:

Electronically: Go to *http://www.regulations.gov* and enter FWS–R2–ES–2017–0036.

Hard copy: Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2017–

0036, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

Public meetings: The locations of the information meetings discussed above in **DATES** are as follows:

1. *Flagstaff:* Northern Arizona University, Prochnow Auditorium, South Knowles Drive, Flagstaff, AZ 86001.

2. *Pinetop:* Hon-Dah Resort, Casino Banquet Hall, 777 AZ–260, Pinetop, AZ 85935.

3. *Truth or Consequences:* Ralph Edwards Auditorium, Civic Center, 400 West Fourth, Truth or Consequences, NM 87901.

4. *Albuquerque:* Crowne Plaza Albuquerque, 1901 University Boulevard NE., Albuquerque, NM 87102.

FOR FURTHER INFORMATION CONTACT: Sherry Barrett, Mexican Wolf Recovery Coordinator, 505–346–2525.

SUPPLEMENTARY INFORMATION:

Background

A primary goal of our endangered species program and the Act (16 U.S.C. 1531 *et seq.*) is endangered or threatened animals and plants recovering to the point where they are again secure, self-sustaining ecosystems members. Recovery means improving listed species' status to the point at which listing is no longer appropriate under the criteria set out in the Act, section 4(a)(1). The Act requires developing recovery plans for listed species, unless such a plan would not promote a particular species' conservation.

The Service has revised its approach to recovery planning; the revised process is called Recovery Planning and Implementation (RPI) (USFWS 09/21/2016). RPI is intended to reduce the time needed to develop and implement recovery plans, increase recovery plan relevancy over a longer timeframe, and add flexibility to recovery plans so they can be adjusted to new information or circumstances. Under RPI, a recovery plan will include statutorily required elements (measurable criteria, site-specific management actions, and estimates of time and costs), along with a concise introduction and our strategy for how we plan to achieve species recovery. The RPI recovery plan is supported by a separate Species Status Assessment (SSA), or in some cases, a species Biological Report, which provides the background information and threat assessment, which are key to recovery plan development. The essential component to flexible implementation under RPI is producing a separate working document called the Recovery Implementation Strategy (implementation strategy). The implementation strategy steps down from the more general description of actions described in the recovery plan to detail the near-term, specific activities needed to implement the recovery plan. The implementation strategy will be adaptable by being able to incorporate new information without having to concurrently revise the recovery plan, unless changes to statutory elements are required. The Mexican wolf implementation strategy document will be developed with partners at a later date. The Mexican Wolf Draft Recovery Plan, First Revision, represents one of the first products developed using RPI.

In addition to the recovery plan and implementation strategy, we have completed a biological report describing the Mexican wolf's current status. The biological report supports the recovery plan by providing the background, life-history, and threat assessment information. The biological report was independently peer-reviewed by scientists outside of the Service and is available at *https://www.regulations.gov* in Docket No. FWS–R2–ES–2017–0036, and also at our Web site: *https://www.fws.gov/southwest/es/mexicanwolf/.* As with the implementation strategy, we will regularly update the biological report as new species status information becomes available, without having to concurrently review the recovery plan.

Species History

The Mexican wolf was originally listed as an endangered subspecies on April 28, 1976 (41 FR 17736), but was subsumed into the listing for the gray wolf in the coterminous United States and Mexico in 1978 (43 FR 9607, March 9, 1978). The Mexican wolf is currently listed as an endangered subspecies throughout its range without critical habitat (80 FR 2488, January 16, 2015). The Mexican wolf is also listed as endangered by the Secretaría de Medio Ambiente y Recursos Naturales, or Federal Ministry of the Environment and Natural Resource (SEMARNAT 2010) in Mexico. Mexican wolves in Arizona and New Mexico are protected under State wildlife statutes as the gray wolf. In Arizona, the gray wolf is on the Arizona Game and Fish Department's list of ''Species of Greatest Conservation Need.'' In New Mexico, the gray wolf is listed as endangered.

In the United States, current Mexican wolf range includes portions of Arizona and New Mexico in an area designated as the Mexican Wolf Experimental Population Area (MWEPA) under the Act, section 10(j) (U.S. Fish and Wildlife Service 2016). The Service began releasing Mexican wolves from captivity into the MWEPA in 1998, marking the first Mexican wolf reintroduction since their extirpation in the late 1970s. As of 2016, there is a single population of at least 113 Mexican wolves in the MWEPA (U.S. Fish and Wildlife Service 2017). In Mexico, the current Mexican wolf range includes the northern portion of the Sierra Madre Occidental in the state of Chihuahua (López González 2017, pers. comm.). After Mexican wolves were extirpated from Mexico in the late 1970s to early 1980s, Mexico began reintroducing the subspecies from captivity back into the wild in 2011. In Mexico, as of April 2017, approximately 28 wolves inhabit the northern portion of the Sierra Madre Occidental Mountains in the state of Chihuahua (Garcia Chavez et al. 2017).

In addition to the wild populations, a Mexican wolf captive population is managed under the Mexican Wolf Species Survival Plan (SSP), administered by the Association of Zoos and Aquariums. The SSP is a binational captive-breeding program with the primary purpose of producing Mexican wolves for reintroduction in the United States and Mexico and conducting public education and research. The captive population is the sole source of Mexican wolves available to reestablish the species in the wild and is, therefore, an essential component of the Mexican wolf recovery effort.

The Mexican wolf is at risk of extinction in the wild primarily because of gunshot-related mortality, inbreeding, loss of heterozygosity, loss of adaptive potential, small population size, and the cumulative effects of the aforementioned threats (80 FR 2488, January 16, 2015). As a result of predator control and eradication efforts in the 20th century, the number of Mexican wolves declined rapidly (Mech and Boitani 2003), but with the capture of the last remaining Mexican wolves in the wild in Mexico, and subsequent addition of several wolves already in captivity, the United States and Mexico established a binational captive-breeding program with seven unrelated ''founders.'' As a result of this small number of founders, Mexican wolves face the aforementioned genetic challenges (U.S. Fish and Wildlife Service 2014).

Recovery Plan Strategy

The overall strategy for recovering the Mexican wolf focuses on improving the two populations' resilience (*i.e.,* population size) and genetic representation, one in the MWEPA in

the United States, and one in the northern portion of the Sierra Madre Occidental in Mexico, across an adequate ecological and geographic range of representation within each population. The strategy involves carefully managing the captive-breeding program, releasing Mexican wolves from the captive-breeding program into the wild, and translocating Mexican wolves from the MWEPA to Mexico, to ensure two genetically and demographically viable populations are extant in the wild for redundancy. In order to achieve the genetic criteria for downlisting and delisting the Mexican wolf in this Plan, the states of New Mexico and Arizona, and the Mexican government, will determine the timing, location and circumstances of releases of wolves into the wild within their respective states, and Mexico, from the captive population, with the Service providing collaborative logistical support and facilitation of those recovery actions.

Under this strategy, Mexican wolves will be managed to achieve an average population size, with an upper population size management boundary applied to the MWEPA that would allow all forms of management to ensure that population growth does not continue unchecked. The population in Mexico will not be managed with an upper boundary. Another key component of the strategy includes working with Federal, State, Tribal, and local partners, and the public, to improve Mexican wolf tolerance on the landscape.

Request for Public Comments

The Act, section 4(f), requires us to provide public notice and an opportunity for public review and comment during recovery plan development. Our policy is to also request peer review of recovery plans (59 FR 34270, July 1, 1994). We will summarize and respond to the issues the public and peer reviewers raise and make our responses available to the public. Substantive comments may or may not result in changes to the recovery plan; comments regarding recovery plan implementation will be forwarded as appropriate to Federal or other entities so that they can be taken into account during the course of implementing recovery actions. Pursuant to a court order, this recovery plan must be finalized by November 30, 2017.

We invite written comments on the draft recovery plan. In particular, we are interested in comments on the recovery strategy, recovery criteria, recovery actions, and the cost estimates associated with implementing the recommended recovery actions.

We make reference throughout the draft recovery plan to locations where more detailed information can be found. Information on the Mexican wolf's life-history needs, threats, current status and future projections, survey guidelines, and conservation efforts to date are detailed in a variety of separate documents, including the biological report the Service developed. These documents can be found at *https://www.regulations.gov* in Docket No. FWS–R2–ES–2017–0036 and also at our Web site: *https://www.fws.gov/southwest/es/mexicanwolf/.*

Before we approve our final recovery plan, we will consider all comments we receive by the date specified in **DATES**. You may submit your comments and materials concerning the draft recovery plan by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in *ADDRESSES*.

Public Availability of Comments

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive will be available, by appointment, for public inspection during normal business hours at our office (see *ADDRESSES*).

References Cited

A complete list of all references cited herein is available at *https://www.regulations.gov* in Docket No. FWS–R2–ES–2017–0036, on our Web site (*https://www.fws.gov/southwest/es/mexicanwolf/*), or upon request from the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

We developed our draft recovery plan under the authority of the Act, section 4(f), 16 U.S.C. 1533(f). We publish this notice under section 4(f) Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.).*

Dated: June 20, 2017.

Benjamin N. Tuggle,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2017–13762 Filed 6–29–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23374; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, National Park Service, Hubbell Trading Post National Historic Site, Ganado, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, National Park Service, Hubbell Trading Post National Historic Site, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Hubbell Trading Post National Historic Site. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Hubbell Trading Post National Historic Site at the address in this notice by July 31, 2017.

ADDRESSES: Lloyd Masayumptewa, Superintendent, Hubbell Trading Post National Historic Site, ½ Mile West of Highway 191 & 264, Ganado, AZ 86505, telephone (928) 755–3475, email *lloyd_masayumptewa@nps.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the U.S. Department of the Interior, National Park Service, Hubbell Trading

Post National Historic Site, Ganado, AZ. The human remains were removed from an unknown location.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the Superintendent, Hubbell Trading Post National Historic Site.

Consultation

A detailed assessment of the human remains was made by Hubbell Trading Post National Historic Site professional staff in consultation with representatives of the Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Pueblo of Laguna, New Mexico; and Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah) (hereafter referred to as ''The Consulted Tribes'').

The following tribes were contacted but did not participate in the face-to-face consultation meetings: Apache Tribe of Oklahoma; Fort McDowell Yavapai Nation, Arizona; Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Pueblo of Acoma, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Tesuque, New Mexico; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Invited Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown location. The human remains were donated by the Hubbell family to the National Park Service in approximately 1967, and are believed to have been displayed in the Trading Post Rug Room by Roman Hubbell. The human remains consist of one human skull of indeterminate age and sex. No known individual was identified. No associated funerary objects are present.

Pursuant to 43 CFR 10.16, the Secretary of the Interior may make a recommendation for a transfer of control of culturally unidentifiable human remains. In December 2016, Hubbell Trading Post National Historic Site requested that the Secretary, through the Native American Graves Protection and Repatriation Review Committee, recommend the proposed transfer of control of the culturally unidentifiable Native American human remains in this notice to the Hopi Tribe of Arizona and Navajo Nation, Arizona, New Mexico & Utah. The Review Committee, acting pursuant to its responsibility under 25 U.S.C. 3006(c)(5), considered the request at its March 2017 meeting and recommended to the Secretary that the proposed transfer of control proceed. An April 2017 letter on behalf of the Secretary of the Interior from the National Park Service Associate Director for Cultural Resources, Partnerships, and Science transmitted the Secretary's independent review and concurrence with the Review Committee that:

- None of The Consulted Tribes or The Invited Tribes objected to the proposed transfer of control, and
- Hubbell Trading Post National Historic Site may proceed with the agreed-upon transfer of control of the culturally unidentifiable human remains to the Hopi Tribe of Arizona and the Navajo Nation, Arizona, New Mexico & Utah.

Transfer of control is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by Hubbell Trading Post National Historic Site

Officials of Hubbell Trading Post National Historical Site have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American, based on osteological analysis.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.
- Pursuant to 43 CFR 10.16, the disposition of the human remains will be to the Hopi Tribe of Arizona and the Navajo Nation, Arizona, New Mexico & Utah.

Additional Requestors and Disposition

Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Lloyd Masayumptewa, Superintendent, Hubbell Trading Post National Historic Site, ½ Mile West of Highway 191 & 264, Ganado, AZ 86505, telephone (928) 755–3475, email *lloyd_masayumptewa@nps.gov,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Hopi Tribe of Arizona and the Navajo Nation, Arizona, New Mexico & Utah may proceed.

Hubbell Trading Post National Historic Site is responsible for notifying The Consulted Tribes and The Invited Tribes that this notice has been published.

Dated: May 9, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13740 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23389; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Oberlin College, Oberlin, OH

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Oberlin College has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Oberlin College. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Oberlin College at the address in this notice by July 31, 2017.

ADDRESSES: Dr. Amy V. Margaris, Oberlin College NAGPRA Compliance Officer, Department of Anthropology,

305 King Building, 10 North Professor Street, Oberlin, OH 44074 telephone (440) 775–5173, email *amy.margaris@oberlin.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of Oberlin College, Oberlin, OH. The human remains were removed from Onondaga County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Oberlin College professional staff in consultation with representatives of the Onondaga Nation.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown site in Baldwinsville, Onondaga County, NY. In 1886, the Oberlin College Museum received human remains described as ''Skull of Onondaga Indian'' acquired from an ''Ancient Burial Place, Baldwinsville, NY.'' S.M. Dunbar is listed as the donor. The human remains were retained by Oberlin College after the museum's closure in the 1950s and are now in the care of the Oberlin College Department of Anthropology. The human remains consist of one probable female, approximately 18–35 years old. ''Onondaga'' is written in black ink on the human remains. No known individuals were identified. No associated funerary objects are present.

Osteological examination identifies these human remains as representing an individual of Native American ancestry. Their geographic affiliation with the territory of the Onondaga Nation is documented through collection evidence, oral history, and scholarly sources. During consultation, the Onondaga Nation's NAGPRA contact, Tony Gonyea, identified Baldwinsville as located in the heart of the traditional area of the Onondaga Nation. Archeological data demonstrate the Onondaga Nation's continued occupation of the Baldwinsville area since at least the Late Woodland period.

Determinations Made by Oberlin College

Officials of Oberlin College have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Onondaga Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Amy V. Margaris, Oberlin College NAGPRA Compliance Officer, Department of Anthropology, 305 King Building, 10 North Professor Street, Oberlin, OH 44074 telephone (440) 775–5173, email *amy.margaris@oberlin.edu,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Onondaga Nation may proceed.

Oberlin College is responsible for notifying the Onondaga Nation that this notice has been published.

Dated: May 11, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13743 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23397; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Human Remains Repository, Department of Anthropology, University of Wyoming, Laramie, WY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Human Remains Repository, Department of Anthropology, University of Wyoming, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Human Remains Repository, Department of Anthropology, University of Wyoming. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Human Remains Repository, Department of Anthropology, University of Wyoming, at the address in this notice by July 31, 2017.

ADDRESSES: Dr. Rick L. Weathermon, Curator, Human Remains Repository, Department 3431, Anthropology, 1000 East University Avenue, University of Wyoming, Laramie, WY 82071, telephone (307) 314–2035, email *rikw@uwyo.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Human Remains Repository, Department of Anthropology, University of Wyoming, Laramie, WY. The human remains were removed from an unknown location in Hamilton County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Human Remains Repository, Department of Anthropology, University of Wyoming, professional staff in consultation with representatives of the Tonkawa Tribe of Indians of Oklahoma. The following Indian Tribes were invited to consult but did not participate in consultation: Apache Tribe of Oklahoma; Comanche Nation, Oklahoma; Jicarilla Apache Nation, New Mexico; Kiowa Indian Tribe of Oklahoma; Mescalero Apache

Tribe of the Mescalero Reservation, New Mexico; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona, and White Mountain Apache Tribe of the Fort Apache Reservation, Arizona.

History and Description of the Remains

At some time in the 1920s, human remains representing, at minimum, one individual were removed from an unknown location in Hamilton County, TX. The fragmentary human remains were given to the Anna Miller Museum in Newcastle, WY, in 1969 and then transferred to the University of Wyoming Anthropology Department Human Remains Repository (Record HR202) in 1993. The human remains represent a single adult male. No known individual was identified. No associated funerary objects are present.

At the time of the excavation and removal of these human remains, the land from which the human remains were removed was not the tribal land of any Indian tribe or Native Hawaiian organization. In January of 2017, the Human Remains Repository, Department of Anthropology, University of Wyoming, initiated consultation with all Indian tribes who are recognized as aboriginal to the area from which these Native American human remains were removed. These tribes are the Comanche Nation, Oklahoma, and the Kiowa Indian Tribe of Oklahoma. None of these Indian tribes responded to the invitation nor agreed to accept control of the human remains. In May of 2017, the Human Remains Repository, Department of Anthropology, University of Wyoming, agreed to transfer control of the human remains to the Tonkawa Tribe of Indians of Oklahoma.

Determinations Made by the Human Remains Repository, Department of Anthropology, University of Wyoming

Officials of the Human Remains Repository, Department of Anthropology, University of Wyoming, have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are reasonably believed to be Native American based on museum notes and characteristic features of the cranial fragments.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11(c)(2)(i), the disposition of the human remains may be to the Tonkawa Tribe of Indians of Oklahoma.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Rick L. Weathermon, Curator, Human Remains Repository, Department 3431, Anthropology, 1000 East University Avenue, University of Wyoming, Laramie, WY 82071, telephone (307) 314–2035, email *rikw@uwyo.edu,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Tonkawa Tribe of Indians of Oklahoma may proceed.

The Human Remains Repository, Department of Anthropology, University of Wyoming, is responsible for notifying the Apache Tribe of Oklahoma; Comanche Nation, Oklahoma; Jicarilla Apache Nation, New Mexico; Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonkawa Tribe of Indians of Oklahoma; Tonto Apache Tribe of Arizona; and White Mountain Apache Tribe of the Fort Apache Reservation, Arizona, that this notice has been published.

Dated: May 12, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13744 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23398; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Texas State University, Center for Archaeological Studies and Department of Anthropology, San Marcos, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Texas State University, Center for Archaeological Studies and Department of Anthropology, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Texas State University, Center for Archaeological Studies and Department of Anthropology. If no additional requestors come forward, the human remains may be reinterred.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Texas State University, Center for Archaeological Studies and Department of Anthropology, at the address in this notice by July 31, 2017.

ADDRESSES: Todd M. Ahlman, Center for Archaeological Studies, Texas State University, 601 University Drive, San Marcos, TX 78666, telephone (512) 245–2724, email *toddahlman@txstate.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Texas State University, Department of Anthropology, San Marcos, TX. The human remains were removed from Hays County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Texas State University, Center for Archaeological Studies and Department of Anthropology, professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Cherokee Nation; Comanche Nation, Oklahoma; Coushatta Tribe of Louisiana; Delaware Nation, Oklahoma; Iowa Tribe of Oklahoma; Jicarilla Apache Nation, New Mexico; Kialegee Tribal Town; Kickapoo Traditional

Tribe of Texas; Kickapoo Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Quapaw Tribe of Indians; The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tonkawa Tribe of Indians of Oklahoma; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma; and Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas) (hereafter listed as ''The Consulted Tribes''). Texas State University, Center for Archaeological Studies and Department of Anthropology, professional staff also consulted with the Miakan-Garza Band of the Coahuiltecan people, a non-federally recognized Indian group.

History and Description of the Remains

In February of 1983, human remains representing, at minimum, two individuals were removed from site 41HY161 in Hays County, TX. The human remains were initially discovered in the fall of 1982 during construction and maintenance of the Texas State University campus. Osteological analysis was conducted by a biological anthropologist from the Southwest Texas State University Department of Sociology and Anthropology (now Texas State University Department of Anthropology), who determined by the context and appearance of the remains that they are most likely of prehistoric Native American ancestry. The human remains from the first burial were very fragmentary. Age and sex could not be determined. The human remains from the second burial were determined to be those of an adult female. No known individuals were identified. No associated funerary objects are present.

In February of 2008 and April of 2009, human remains representing, at minimum, four individuals were removed from site 40HY163 in Hays County, TX. The human remains were discovered during a construction project for expansion of the City of San Marcos' Wonder World Drive and later excavated by Texas State University's Center for Archaeological Studies. Osteological analysis was conducted Kyra Stull, M.A. and Dr. Michelle Hamilton of the Department of Anthropology at Texas State University, who determined them to be of prehistoric Native American ancestry. The human remains consist of one adult male, two adult females, and one possible adult female. No known individuals were identified. No associated funerary objects are present.

Pursuant to 43 CFR 10.16, the Secretary of the Interior may recommend that culturally unidentifiable human remains with no ''tribal land'' or ''aboriginal land'' provenience be reinterred under State or other law. In January 2017, the Texas State University, Center for Archaeological Studies and Department of Anthropology, requested that the Secretary, through the Native American Graves Protection and Repatriation Review Committee, recommend the proposed re-interment of the culturally unidentifiable Native American human remains in this notice, according to State or other law. The Review Committee, acting pursuant to its responsibility under 25 U.S.C. 3006(c)(5), considered the request at its March 2017 meeting and recommended to the Secretary that the proposed re-interment proceed. An April 2017 letter on behalf of the Secretary of Interior from the National Park Service Associate Director for Cultural Resources, Partnerships, and Science transmitted the Secretary's independent review and concurrence with the Review Committee that:

- None of The Consulted Tribes objected to the proposed re-interment, and
- Texas State University, Center for Archaeological Studies and Department of Anthropology, may proceed with the proposed re-interment of the culturally unidentifiable human remains.

Re-interment is contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Determinations Made by the Texas State University, Center for Archaeological Studies and Department of Anthropology

Officials of the Texas State University, Center for Archaeological Studies and Department of Anthropology, have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on association with prehistoric artifacts and ancestry estimation.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Pursuant to 43 CFR 10.11(c)(1), a ''tribal land'' or ''aboriginal land'' provenience cannot be ascertained.
- Pursuant to 43 CFR 10.10(g)(2)(ii) and 43 CFR 10.16, the human remains may be reinterred according to the law of the State of Texas and the City of San Marcos, Texas.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Todd M. Ahlman, Center for Archaeological Studies, Texas State University, 601 University Drive, San Marcos, TX 78666, telephone (512) 245–2724, email *toddahlman@txstate.edu,* by July 31, 2017. After that date, if no additional requestors have come forward, the human remains may be reinterred.

The Texas State University, Center for Archaeological Studies and Department of Anthropology, is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: May 12, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13741 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23403; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Defense, Department of the Air Force, Air Education and Training Command, Barry M. Goldwater Range East, 56th Range Management Office, Luke Air Force Base, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Defense, Department of the Air Force, Air Education and Training Command, Barry M. Goldwater Range East, 56th Range Management Office, Luke Air Force Base, has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural

affiliation between the human remains and associated funerary objects and present-day Indian tribes. Lineal descendants or representatives of any Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the 56th Range Management Office, Luke Air Force Base. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to lineal descendants or Indian tribes stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the 56th Range Management Office, Luke Air Force Base by July 31, 2017.

ADDRESSES: Mr. Charles Buchanan, Director, 56th Range Management Office, 7101 Jerstad Lane, Building 500, Luke Air Force Base, AZ 85309, phone (623) 856–5820, email *charles.buchanan@us.af.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the 56th Range Management Office, Luke Air Force Base, and in physical custody of the Arizona State Museum, Tucson, AZ. The human remains and associated funerary objects were removed from site AZ Y:8:001 (ASM), Maricopa County, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the Department of the Air Force, 56th Range Management Office, Luke Air Force Base, which has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Arizona State Museum and the 56th Range Management Office, Luke Air Force Base, professional staff in consultation with representatives of the Ak Chin Indian Community (previously listed as the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Gila River Indian Community of the Gila River Indian Reservation, Arizona; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona. The following Indian tribes were invited to consult but did not participate in consultations: The Cocopah Tribe of Arizona; Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Fort McDowell Yavapai Nation, Arizona; Fort Mohave Indian Tribe of Arizona, California & Nevada; Hopi Tribe of Arizona; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona); and Zuni Tribe of the Zuni Reservation, New Mexico. All tribes listed are referred to as the ''Invited and Consulted Tribes.''

History and Description of the Remains

On September 21, 1978, human remains representing, at minimum, one individual were removed from site AZ Y:8:001 (ASM) on the Barry M. Goldwater Range East, Maricopa County, AZ (formerly the Luke AFB Bombing and Gunnery Range). The human remains, Cremation 1, were removed from Component 2, during an authorized archeological excavation under the direction of Dr. Bruce Huckell, Arizona State Museum, AZ. The collection was transferred to the Arizona State Museum on September 28, 1978, where it is currently curated. A professional report on the collection was published in 1979: *The Coronet REAL Project: Archaeological Investigations on the Luke Range, Southwestern Arizona,* by Bruce B. Huckell. Arizona State Museum Archaeological Series No. 129.

The estimated age of the individual at death is older than 40 years based on dentition and ectocranial suture of the sagittal suture. The sex of the cremation was determined to be male based on evidence from the skull and in nominate. The stature of the individual is indeterminate due to the fragmentary nature of the long bones. No known individuals were identified. The 21 associated funerary objects include 1 reconstructed Tanque Verde Red-on-Brown ceramic pitcher with missing handle (1979–145–1); 1 lot of sherds of a burned Colorado Red bowl (1979–145–10); 1 bone awl (1979–145–6); 3 rim sherds of a burned Tonto Polychrome bowl (1979–145–7:x); 14 body sherds of the same burned Tonto Polychrome bowl (1979–145–8:x), and 1 piece of worked animal bone (None–1979–145–C1–01).

Based on morphological characteristics, geographic location, archeological context, and the presence of culturally and temporally identifiable ceramics, and consistency in cremation pit size and orientation, the human remains have been determined to be Native American dating to the Classic period (A.D. 1150–1450) Tucson Basin Hohokam. The cremation pit and orientation of the remains (the long-axis of the body was aligned east-west, with the head at the east) are consistent with Classic Period Hohokam sites in the Gila Bend area and Tucson Basin. The cremation pit is identical in size and shape with primary cremations from site AZ AA:12:46 (ASM), the Rabid Ruin, a Tucson Basin Hohokam site.

A relationship of shared group identity can reasonably be traced between members of the Hohokam culture and the four southern O'odham tribes of Arizona. The O'odham comprise four Federally recognized Indian tribes (Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Gila River Indian Community of the Gila River Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and Tohono O'odham Nation of Arizona. Historically the Pimeria Alta is the traditional homeland of the O'odham; including the river people (Akimel), the desert people (Tohono) and the sand people (Hia C-ed O'odham). O'odham oral history teaches that the O'odham were created in this land and have always lived here. Places mentioned in the Creation Story and other stories and songs have been identified on the landscape throughout the Sonoran Desert.

A relationship of shared group identity may also reasonably be traced between members of the Hohokam culture of the Phoenix Basin and clans of the Hopi Tribe of Arizona. Hopi history is based, in large part, on clan migration narratives. The Hopi consider all of Arizona to be within traditional Hopi lands, *i.e.,* areas in and through which Hopi clans are believed to have migrated in the past. Hopi oral history and the anthropological record show that some clans originated in the Salt-Gila region and were descended from the Hohokam. After the fall of the Great House communities, Hohokam refugees were absorbed into the Hopi culture.

A relationship of shared group identity can also reasonably be traced between members of the Hohokam

culture and the Zuni Tribe of the Zuni Reservation, New Mexico. Zuni oral history tells of ancestral migrations and settling throughout this region in their search for the Middle Place of the World (present day Pueblo of Zuni). Zuni ancestors left many markers of their passing including trails, habitation sites, campsites, and burials. Elders have identified features in the area, including shrines and petroglyphs, as Zuni.

A relationship of shared group identity may also be reasonably be traced between members of the Patayan culture and the Quechan tribe of the Fort Yuma Indian Reservation, California & Arizona. The Colorado Red bowl is associated with the archeological culture identified as Patayan, which the Quechan believe were their ancestors.

Determinations of the Luke Air Force Base

Officials of the 56th Range Management Office, Luke Air Force Base have determined that:

- Pursuant to 25 U.S.C. 301(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 301(3)(A), the 21 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 301(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Ak Chin Indian Community (previously listed as the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Mr. Charles Buchanan, Director, 56th Range Management Office, Barry M. Goldwater Range East, 7101 Jerstad Lane, Luke Air Force Base, AZ 85309, phone (623) 856–8520, email *charles.buchanan@us.af.mil,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico, may proceed.

The 56th Range Management Office, Luke Air Force Base, is responsible for notifying the Invited and Consulted Tribes that this notice has been published.

Dated: May 15, 2017.

Melanie, O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13736 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23414; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Agriculture, Forest Service, Deschutes National Forest, Bend, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture, Forest Service, Deschutes National Forest has completed an inventory of human remains, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian tribes or Native Hawaiian organizations. Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Deschutes National Forest. If no additional requestors come forward, transfer of control of the human remains to the Indian tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Deschutes National Forest at the address in this notice by July 31, 2017.

ADDRESSES: John Allen, Deschutes National Forest, 63095 Deschutes Market Road, Bend, OR 97701, telephone (541) 383–5512, email *jpallen@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Deschutes National Forest, Bend, OR. The human remains were removed from Federal lands in central Oregon.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Deschutes National Forest professional staff, with assistance by the University of Oregon, Department of Anthropology, in consultation with representatives of the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes.

History and Description of the Remains

In 1989, human remains representing, at minimum, three individuals were removed from individual homes of persons arrested for violations of the Archeological Resource Protection Act. The three individuals were apprehended while looting an archeological site on the Deschutes National Forest. Pre-contact human remains were discovered during a search of the individuals' residences. The Deschutes National Forest is unable to determine the exact provenience of the human remains, other than their origination from Federal lands in central Oregon. The human remains remained in possession of Federal law enforcement until 1997, when they were returned to the Deschutes National Forest. In 2009, the Deschutes National

Forest contracted with Dr. Robert Pastor at the University of Oregon for the purpose of determining the number of individuals represented in the collection. Dr. Pastor determined that the set of human remains was comprised of three individuals. Individual 1 is identified as an adult male approximately 35–49 years of age, and of Amerindian ancestry. Individual 2 is identified as a young adult female between 15 and 19 years of age and of Amerindian ancestry. Individual 3 is identified as a juvenile of between 6 and 10 years of age and of Amerindian ancestry. No known individuals were identified. There are no associated funerary objects associated with the three individuals.

Determinations Made by the Deschutes National Forest

Officials of the Deschutes National Forest have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on the analysis performed by the University of Oregon Department of Anthropology.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes.

Additional Requestors and Disposition

Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to John Allen, Deschutes National Forest, 63095 Deschutes Market Road, Bend, OR 97701, telephone (541) 383–5512, email *jpallen@fs.fed.us,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes may proceed.

The Deschutes National Forest is responsible for notifying the Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon), Confederated Tribes of the Warm Springs Reservation of Oregon, and Klamath Tribes that this notice has been published.

Dated: May 16, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13738 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23306; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Arkansas Archeological Survey, Fayetteville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Arkansas Archeological Survey, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Arkansas Archeological Survey. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Arkansas Archeological Survey at the address in this notice by July 31, 2017.

ADDRESSES: Dr. George Sabo, Director, Arkansas Archeological Survey, 2475 North Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Arkansas Archeological Survey that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1972, three cultural items were removed from the Cryer Field site (3LA35) in Lafayette County, AR. The 3 unassociated funerary objects are one Handy Engraved bottle, one Washington Stamped jar, and one Pease Brushed-Incised jar (Cat. 72–406–68–1, 2, 3).

The pottery types are well-known examples of Caddo tradition wares. All are contemporaneous, ranging from A.D. 1300 to 1500, and are attributed to the Haley Phase of the Middle Caddo period. These pottery types are found throughout Southwest Arkansas, and into adjoining corners of Texas, Louisiana, and Oklahoma. All three cultural items were made before European contact and during the Caddo tradition.

The Caddo archeological tradition developed between A.D. 900 and 1000 in the four corners region of Arkansas, Texas, Louisiana, and Oklahoma. Distinctive characteristics include a dispersed residential settlement of families with a lifestyle grounded in farming and collecting wild plants and animals. The core of community life was a religious and political center with ceremonial and burial mounds, public areas for community events and rituals, and a small residential population

believed to be religious and political leaders and their families. Caddo ceramics are highly distinctive with dual manufacturing traditions that produced both refined wares decorated with complex stylized incised and engraved designs and utilitarian wares with highly plastic incised, punctated, and brushed designs that are dominated by geometric motifs.

The Caddo continued to practice traditional settlement arrangements and material crafts well into the contact period. This is confirmed in part by past discoveries of distinctive Caddo ceramics and other artifacts found with European trade items in locations where French and Spanish observers documented their settlements. There is thus a strong material link between historic Caddo Tribal communities and pre-contact archeological remains. The collection enumerated here is entirely typical of pre-contact Caddo Tradition material culture.

Determinations Made by the Arkansas Archeological Survey

Officials of the Arkansas Archeological Survey have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 3 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Caddo Nation of Oklahoma.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. George Sabo, Director, Arkansas Archeological Survey, 2475 North Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556 by July 31, 2017. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Caddo Nation of Oklahoma may proceed.

The Arkansas Archeological Survey is responsible for notifying the Caddo Nation of Oklahoma that this notice has been published.

Dated: April 26, 2017.

Melanie O'Brien,

Program Manager.

[FR Doc. 2017–13742 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23400; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Massachusetts Amherst, Department of Anthropology, Amherst, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Massachusetts Amherst, Department of Anthropology, has completed an inventory of human remains, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology at the University of Massachusetts, Amherst. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the address in this notice by July 31, 2017.

ADDRESSES: Dr. Sonya Atalay, Chair, Repatriation Committee, Department of Anthropology, 217 Machmer Hall, University of Massachusetts, 240 Hicks Way, Amherst, MA 01003, telephone (413) 545–2702, email *satalay@umass.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the University of Massachusetts Amherst, Department of Anthropology. The human remains were removed from an unknown location in East Springfield, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the University of Massachusetts Amherst, Department of Anthropology, professional staff in consultation with representatives of the Haudenosaunee Standing Committee on Burial Rights and Regulations, and the following federally-recognized tribes: Cayuga Nation; Oneida Nation; Oneida Nation of New York; Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation (hereinafter known as the Haudenosaunee Confederacy).

History and Description of the Human Remains

In the 1950s, human remains representing, at minimum, one individual were removed from the farm of Harriet R. and Raymond Rogers in East Springfield, Otsego County, NY. After keeping the human remains several years, a farmer transferred possession to an artist who visited the farm. That artist later learned about NAGPRA and transferred the human remains to the University of Massachusetts, Department of Anthropology. The date of this transfer was not recorded. No known individual was identified. No associated funerary objects are present.

Also in the possession of the University of Massachusetts, Department of Anthropology are human remains representing, at minimum, one individual from an unknown provenience, represented by the vault portion of the cranium (top, sides and back of the head). The following identification is written on the back of the cranium in black ink: ''Prehistoric Iriquois [sic] UU 21524/2.'' No known individual was identified. No associated funerary objects are present.

No further contextual information accompanies either set of human remains. Both have remained in the possession of the University of Massachusetts since legal control was established.

Determinations Made by the University of Massachusetts Amherst, Department of Anthropology

Officials of the University of Massachusetts Amherst, Department of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Haudenosaunee Confederacy.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a formal written request with information in support of the claim to Dr. Sonya Atalay, Chair, Repatriation Committee, Department of Anthropology, 217 Machmer Hall, University of Massachusetts, 240 Hicks Way, Amherst, MA 01003, telephone (413) 545–2702, email *satalay@umass.edu* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Haudenosaunee Confederacy may proceed.

The University of Massachusetts Amherst, Department of Anthropology, is responsible for notifying the Haudenosaunee Standing Committee on Burial Rights and Regulations and the member nations of the Haudenosaunee Confederacy that this notice has been published.

Dated: May 12, 2017.

Melanie O'Brien,

National NAGPRA Program Manager.

[FR Doc. 2017–13737 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–23301; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Museum of Natural History and Planetarium, Roger Williams Park, Providence RI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Museum of Natural History and Planetarium, Roger Williams Park, has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Museum of Natural History and Planetarium, Roger Williams Park. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Museum of Natural History and Planetarium, Roger Williams Park, at the address in this notice by July 31, 2017.

ADDRESSES: Michael W. Kieron, Museum of Natural History and Planetarium, Roger Williams Park, 1000 Elmwood Avenue, Providence, RI 02907, telephone (401) 680–7248, email *m.kieron@musnathist.com.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Museum of Natural History and Planetarium, Roger Williams Park. The human remains and associated funerary objects were removed from the Miller Cave site (23PU2) in Pulaski County, MO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Museum of Natural History and Planetarium, Roger Williams Park, professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Comanche Nation, Oklahoma; Eastern Band of Cherokee Indians; Kiowa Indian Tribe of Oklahoma; and The Osage Nation (previously listed as the Osage Tribe).

History and Description of the Remains

In 1927, human remains representing, at minimum, one individual were removed from the Miller Cave site (23PU2) in Pulaski County, MO, by Mr. and Mrs. Edward H. Nadeau. The human remains, consisting of one adult metacarpal, and the associated funerary objects were donated to the Museum of Natural History and Planetarium, Roger Williams Park, by Mr. and Mrs. Nadeau on January 23, 1933. No known individuals were identified. The 16 associated funerary objects include 1 polished tip of a white-tailed deer antler, 1 partial white-tailed deer antler, 9 partial white-tailed deer bones, 1 piece of a spiny softshell turtle carapace, and 4 potsherds. Most of the objects were labeled as being from Miller Cave, Pulaski County, MO.

The human remains and associated funerary objects were part of a collection of 50 lots of American Indian objects and geological specimens collected in the 1920s by the Nadeaus. No records related to this donation have been located.

The human remains and associated funerary objects were accessioned (catalog number E2730, accession number 8943) and stored with objects collected in 1927 from North Carolina and Young County, Texas. The objects from North Carolina and Texas were labeled according to their provenience. The entire group was entered into the catalog as ''Bones and Potsherds, Pulaski Co., Missouri; Young Co., Texas; North Carolina.'' Many of the American Indian objects donated at this time were

treated in a similar manner, with objects from disparate localities being cataloged together.

Due to this generalized catalog entry, the human remains were originally reported by the Museum of Natural History and Planetarium in an inventory as culturally unidentifiable (CUI). A 1983 study identified the human remains as American Indian based on the associated funerary objects. Following an examination by representatives of The Osage Nation (previously listed as the Osage Tribe) in January 2016, The Osage Nation and the Museum of Natural History and Planetarium, Roger Williams Park concurred that the human remains and associated funerary objects are from a burial site located on Osage ancestral lands.

Determinations Made by the Museum of Natural History and Planetarium, Roger Williams Park

Officials of the Museum of Natural History and Planetarium, Roger Williams Park, have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 1 individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 16 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Osage Nation (previously listed as the Osage Tribe).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Michael W. Kieron, Museum of Natural History and Planetarium, Roger Williams Park, 1000 Elmwood Avenue, Providence, RI 02907, telephone (401) 680–7248, email *m.kieron@musnathist.com,* by July 31, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Osage Nation (previously listed as the Osage Tribe) may proceed.

The Museum of Natural History and Planetarium, Roger Williams Park, is responsible for notifying the Apache Tribe of Oklahoma; Comanche Nation, Oklahoma; Eastern Band of Cherokee Indians; Kiowa Indian Tribe of Oklahoma; and The Osage Nation (previously listed as the Osage Tribe) that this notice has been published.

Dated: April 24, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017–13739 Filed 6–29–17; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1035]

Certain Liquid Crystal Ewriters and Components Thereof; Commission Determination Not To Review an Initial Determination Terminating the Last Remaining Respondent Based on Withdrawal of the Complaint; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 11) issued by the presiding administrative law judge (''ALJ'') on May 31, 2017, terminating the last remaining respondent based on a withdrawal of the complaint. The Commission requests written submissions, under the schedule set forth below, on remedy, public interest, and bonding concerning a previously defaulted respondent.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 13, 2017, based on a complaint filed by Kent Displays, Inc. (''Kent Displays'') of Kent, Ohio. 82 FR 4418. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain liquid crystal eWriters and components thereof that infringe U.S. Patent Nos. 7,351,506 and 8,947,604. *Id.* The Commission's notice of investigation named as respondents Shenzhen Howshow Technology Co., Ltd., d/b/a Shenzhen Howshare Technology Co., Ltd., d/b/a Howshare (''Howshare'') of Shenzhen, China, and Shenzhen SUNstone Technology Co., Ltd., d/b/a iQbe (''iQbe'') of Shenzhen, China. *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On April 11, 2017, the ALJ issued an ID finding iQbe in default for failing to respond to the complaint, the notice of investigation, and multiple discovery requests, and for failing to respond to an order to show cause why it should not be found in default. Order No. 9, *not reviewed,* Notice (May 11, 2017).

On May 24, 2017, Kent Displays moved to terminate the investigation with respect to Howshare based on a withdrawal of the complaint. On May 26, 2017, Howshare responded that it did not oppose its termination from the investigation.

On May 31, 2017, the ALJ issued the subject ID, granting the motion and terminating the investigation with respect to Howshare. Order No. 11. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

On June 1, 2017, Kent Displays filed a declaration seeking relief against the defaulted respondent iQbe pursuant to section 337(g)(1) and Commission Rule 210.16(c), 19 CFR 210.16(c). The declaration contains Kent Displays' views on remedy, the public interest, and bonding. A proposed limited exclusion order and a proposed cease and desist order are attached to the declaration.

Section 337(g)(1) and Commission Rule 210.16(c) authorize the Commission to order relief against a respondent found in default, unless, after considering the public interest, it finds that such relief should not issue.

In connection with the final disposition of this investigation, the

Commission may: (1) Issue an order that could result in the exclusion of articles manufactured or imported by iQbe; and/or (2) issue cease and desist orders that could result in iQbe being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors that the Commission will consider include the effect that the exclusion order and/or cease and desists orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Kent Displays is requested to state the HTSUS numbers under which the accused products are imported, to state the dates that the patents expire, and to supply information concerning the identity of any known importers.

Written submissions must be filed no later than the close of business on July 10, 2017. Reply submissions must be filed no later than the close of business July 17, 2017. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadline stated above and submit eight true paper copies to the Office of the Secretary pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–1035'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 26, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–13686 Filed 6–29–17; 8:45 am]

BILLING CODE 7020–02–P

[1] All contract personnel will sign appropriate nondisclosure agreements.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–287 (Second Review)]

Raw In-Shell Pistachios From Iran

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on raw in-shell pistachios from Iran would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted this review on April 1, 2016 (81 FR 18882) and determined on July 5, 2016 that it would conduct a full review (81 FR 45306, July 13, 2016). Notice of the scheduling of the Commission's review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on December 15, 2016 (81 FR 90867) (as revised effective March 7, 2017 (82 FR 14031, March 16, 2017)). The hearing was held in Washington, DC, on April 27, 2017, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on June 26, 2017. The views of the Commission are contained in USITC Publication 4701 (June 2017), entitled *Raw In-Shell Pistachios from Iran: Investigation No. 731–TA–287 (Second Review).*

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

By order of the Commission.

Issued: June 26, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–13715 Filed 6–29–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–979]

Certain Radio Frequency Identification (''RFID'') Products and Components Thereof; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge (''ALJ'') has issued a Final Initial Determination and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation. The ALJ recommended only a limited exclusion order with a certification provision directed against certain infringing radio frequency identification (''RFID'') products and components thereof imported by Respondents Kapsch TrafficCom IVHS, Inc. of McLean, Virginia; Kapsch TrafficCom Holding Corp. of McLean, Virginia; Kapsch TrafficCom Canada, Inc. of Mississauga, Ontario, Canada; Star Systems International, Ltd. of Kwai Chung, Hong Kong; and STAR RFID Co., Ltd. of Bangkok, Thailand. This notice is soliciting public interest comments from the public only.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in its investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on June 22, 2017. Comments should address whether issuance of an exclusion order and/or cease and desist orders in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the recommended orders;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) Explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on July 28, 2017.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to Commission Rule 210.4(f), 19 CFR part 210.4(f). Submissions should refer to the investigation number (''Inv. No. 979'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR part 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: June 27, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–13752 Filed 6–29–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Employment and Training Administration Program Year (PY) 2017; Workforce Innovation and Opportunity Act (WIOA) Section 167, National Farmworker Jobs Program (NFJP) Allocations

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This Notice announces allocations for Program Year (PY) 2017 for the WIOA Title I Section 167 National Farmworker Jobs Program (NFJP) program as required under Section 182(d) of the Workforce Innovation and Opportunity Act of 2014.

The NFJP allocations are distributed to the state service areas by a formula that estimates, by State, the relative demand for NFJP services. The formula factors used to allocate funds for the NFJP were published in the **Federal Register** on May 19, 1999. The notice explained the purpose of the formula; *i.e.,* distributing funds geographically by State service area on the basis of each area's relative share of farmworkers who are eligible for enrollment in the NFJP. The data used in the formula are comprised of a combination of data sets that were selected to yield the relative share distribution across States of eligible farmworkers. While the data factors used in the formula remain unchanged since their development in 1999, the data sets were last updated in 2005 with data from the 2000 Census, the 2003 National Agricultural Workers Survey (NAWS), and the 2002 Census of Agriculture.

DATES: The PY 2017 NFJP allocations become effective for the program year beginning on July 1, 2017.

ADDRESSES: Questions on the allocations can be submitted to the Employment and Training Administration, Office of Financial Administration, 200 Constitution Ave. NW., Room N–4702, Washington, DC 20210, Attention: Ms. Anita Harvey, (202) 693–3958 (phone), (202) 693–2859 (fax), or email: *Harvey.anita@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Laura Ibañez, Unit Chief (202) 693–3645 or Steven Rietzke, Division Chief (202) 693–3912. Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY–TDD).

SUPPLEMENTARY INFORMATION: The Department of Labor (DOL or Department) is announcing final PY 2017 allocations for the NFJP. This notice provides information on the amount of funds available during PY 2017 to State service areas awarded grants through the PY 2016 Funding Opportunity Announcement (FOA) for the National Farmworker Jobs Program (NFJP) Employment and Training and Housing Assistance Grants. The allocations are based on the funds appropriated in the Consolidated Appropriations Act, 2017, Public Law 115–31, May 5, 2017 (from this point forward, referred to as ''the Act''). In appropriating these funds, Congress provided $75,885,000 for Employment and Training Grants; $5,517,000 for Housing Assistance Grants; and $494,000 for Technical Assistance and Training. The Act, Division H, Title I, sec. 106(b), allows the Secretary to set aside up to 0.5 percent of each discretionary appropriation for activities related to program integrity. For 2017, the Department set aside the full 0.5 percent of most discretionary appropriations, including migrant and seasonal farmworker program formula grants and housing. This reduced the amount available for NFJP Employment and Training grants to $75,505,575 and Housing Assistance grants to $5,489,415. The amount appropriated for discretionary purposes (technical assistance and training) was not adjusted. Included below is the table listing the PY 2017 allocations for the NFJP Employment and Training Grants, as well as the sub-allocation table for California. California is the only State service area with more than one grant; the current sub-allocation formula for California was developed in collaboration with the existing grantees. Individual grants are awarded for Housing Assistance as a result of the grants competition and are further distributed according to language in the appropriations law requiring that of the total amount available, not less than 70 percent shall be allocated to permanent housing activities, leaving not more than 30 percent to temporary housing activities.

PY 2017 Formula Allocation for NFJP

The calculation of the PY 2017 formula allocation distribution incorporates the state-by-state relative shares of eligible farmworkers developed for the PY 2005 formula allocations using the updated datasets described above, with various adjustments applied since that time. The PY 2005 calculation adjusted those state-by-state relative shares by ''hold-harmless'' and ''stop-loss''/''stop-gain'' limits due to the introduction of the updated data. The following year, the PY 2006 formula allocations were proportionately based on the PY 2005 formula allocations and further adjusted by an additional $3.8 million appropriated by Congress for States whose PY 2005 allocation had been reduced as a result of the updated data used for the PY 2005 formula allocation distribution. Detailed descriptions of the formula methodology for PY 2005 and PY 2006 formula allocations were provided in the applicable **Federal Register** announcements. The PY 2007 appropriation for the WIA Section 167 formula program was $470 less than the corresponding PY 2006 appropriation. To maintain stability of funding for the program and consistency with the PY 2006 congressional directions to the Department, the Department distributed the PY 2007 formula funding among all States in the same proportion as the distribution of the PY 2006 formula allocations. In all subsequent appropriations, including PY 2017, the Department continued to distribute the formula funding amount in the same proportion as the distribution of the prior year's formula amounts.

State Combinations

There will be a single plan of service for operating the PY 2017 NFJP in the State service areas of Delaware and Maryland and the State service areas of Rhode Island and Connecticut. The sub-allocations for multiple sub-state service areas in California were discussed earlier in this Notice.

PY 2018 Formula Allocation for NFJP

In February and April 2017, the Employment and Training Administration (ETA) hosted a national online dialogue to gather ideas from NFJP grantees, research analysts, economists, and other professionals on revising the existing formula and its databases to ensure incorporation of the latest available data, as required under WIOA Section 182(a). The ideas suggested by the multiple stakeholders who participated in the national online dialogue helped inform the proposed formula for PY 2018. ETA will publish the PY 2018 proposed allocation formula for comment in the fall of 2017.

Byron Zuidema,

Deputy Assistant Secretary for Employment and Training.

[FR Doc. 2017–13750 Filed 6–29–17; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Concrete and Masonry Construction Standard

ACTION: Notice.

SUMMARY: On June 30, 2017, the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Concrete and Masonry Construction Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before July 31, 2017.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201704-1218-003* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Concrete and Masonry Construction Standard information collection. An Occupational Safety and Health Act (OSH Act) covered construction firm engaged in the erection of concrete formwork must post warning signs/barriers, in accordance with regulations 29 CFR 1926.701(c)(2), to reduce exposure of non-essential employees to the hazards of post-tensioning operations. Paragraphs 29 CFR 1926.702(a)(2), (j)(1), and (j)(2) are general lockout/tagout measures to protect workers from injury associated with equipment and machinery. Paragraph 29 CFR 1926.703(a)(2) requires an employer to make available drawings or plans for jack layout, formwork, working decks and scaffolds. Paragraph 1926.705(b) requires an employer to mark the rated capacity of jacks and lifting units. OSH Act section 6(b)(7) authorizes this information collection. *See* 29 U.S.C. 655(b)(7).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0095.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on June 30, 2017. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 24, 2017 (82 FR 11658).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0095. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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.

Agency: DOL–OSHA.

Title of Collection: Concrete and Masonry Construction Standard.

OMB Control Number: 1218–0095.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 798,160.

Total Estimated Number of Annual Responses: 159,632.

Total Estimated Annual Time Burden: 12,771 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: June 27, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–13798 Filed 6–29–17; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Wage and Hour Division (WHD) sponsored information collection request (ICR) titled, ''Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act,'' to the Office of Management and Budget (OMB) for review and approval for continued use,

without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before July 31, 2017.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201701-1235-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–WHD, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act (MSPA) information collection. Agricultural employers, associations, and farm labor contractors use this information collection to make MSPA required disclosures of employment terms and conditions, wage statements, and housing terms and conditions to migrant and seasonal agricultural workers. MSPA section 201 authorizes this information collection. *See* 29 U.S.C. 1821.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1235–0002.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on June 30, 2017. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 23, 2016 (81 FR 84619).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1235–0002. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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.

Agency: DOL–WHD.

Title of Collection: Disclosures to Workers Under the Migrant and Seasonal Agricultural Worker Protection Act.

OMB Control Number: 1235–0002.

Affected Public: Private Sector—businesses or other for-profits and farms.

Total Estimated Number of Respondents: 105,587.

Total Estimated Number of Responses: 82,429,923.

Total Estimated Annual Time Burden: 1,387,659 hours.

Total Estimated Annual Other Costs Burden: $3,296,743.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: June 27, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–13797 Filed 6–29–17; 8:45 am]

BILLING CODE 4510–27–P

NATIONAL CREDIT UNION ADMINISTRATION

Request for Comment Regarding Revised Overhead Transfer Rate Methodology

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: In a voluntary effort to invite input from stakeholders, the NCUA Board (Board) is seeking comments on proposed changes to the Overhead Transfer Rate (OTR) methodology. The primary goal of the proposed changes are to reduce the complexity of the OTR methodology. The proposed changes would also reduce the resources needed to administer the OTR. This document provides a summary of and response to comments received on the current OTR methodology, and explains and solicits comments on the proposed changes to the OTR methodology.

DATES: Comments must be received on or before August 29, 2017 to ensure consideration.

ADDRESSES: You may submit comments by any one of the following methods (Please send comments by one method only):

- *NCUA Web site*: *https://www.ncua.gov/about/pages/board-comments.aspx.*
- *Email*: Address to *boardcomments@ncua.gov.* Include ''[Your name]—Comments on OTR Methodology'' in the email subject line.
- *Fax*: (703) 518–6319. Use the subject line described above for email.
- *Mail*: Address to Gerald Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

• *Hand Delivery/Courier*: Same as mailing address.

Public Inspection: You can view all public comments on NCUA's Web site at *https://www.ncua.gov/about/pages/board-comments.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's headquarters at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6360 or send an email to *EIMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Russell Moore or Julie Decker, Loss/Risk Analysis Officers, Office of Examination and Insurance, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314 or telephone: (703) 518–6383 or (703) 518–6384.

SUPPLEMENTARY INFORMATION: NCUA requested comments on the current OTR methodologies and processes through a notice in the **Federal Register** published on January 27, 2016.[1] Areas the Board specifically sought comments on included:

• Whether the OTR should continue to be determined using a formula-driven approach, or instead be set largely at the discretion of the Board;

• the definition NCUA uses for insurance-related activities;

• adjustments or changes to the current calculation; and

• alternate methodologies to arrive at an accurate and fair allocation of costs.

Within the 90-day comment period, NCUA received 40 comment letters on the OTR methodology. The commenters included federally insured state-chartered credit unions, national credit union trade organizations, state leagues, and state supervisory authorities. There were no comment letters received from federal credit unions. While there were only 40 comment letters, the comments addressed a broad range of complex issues. In addition to reviewing comments for input on the existing approach, NCUA staff explored options for the Board to consider for improving the OTR methodology. Many of the comment letters discussed the methodologies for both the OTR and the Operating Fee as well as other budget-related issues. This request for comments focuses specifically on the OTR methodology. Comments related to the Operating Fee methodology and other budget-related issues were referred to the appropriate office.

Based on the comments and NCUA's internal assessment, the Board is considering changes to the OTR methodology.

Table of Contents

I. Background

NCUA administers the Federal Credit Union Act (the Act), which is comprised of three Titles: Title I—General Provisions, Title II—Share Insurance, and Title III—Central Liquidity Facility. The agency's mission is to ''provide, through regulation and supervision, a safe and sound credit union system, which promotes confidence in the national system of cooperative credit.'' [2] This includes protecting member rights and deposits. Specifically, NCUA charters, regulates, and insures shares in federal credit unions and insures shares and deposits in federally insured state-chartered credit unions through the National Credit Union Share Insurance Fund (Share Insurance Fund).

NCUA is responsible for ensuring federally insured credit unions operate safely and soundly and comply with all applicable laws and regulations within NCUA's jurisdiction.[3] In so doing, the agency mitigates risk to the Share Insurance Fund and prevents taxpayer-funded bailouts.

To achieve its statutory mission, the agency incurs various expenses, including those involved in examining and supervising federally insured credit unions. The Board adopts an Operating Budget each year to fund the vast majority of the costs of operating the agency.[4] The Act authorizes two primary sources to fund the Operating Budget: (1) Requisitions from the Share Insurance Fund; and (2) Operating Fees charged to federal credit unions.[5]

In 1972, the Government Accountability Office recommended NCUA adopt a method for properly allocating Operating Budget costs—that is the portion to be funded by requisitions from the Share Insurance Fund and the portion to be covered by Operating Fees paid by federal credit unions.[6] NCUA has since used an allocation methodology, known as the OTR, to determine how much of the Operating Budget to fund with a requisition from the Share Insurance Fund.

NCUA has employed various allocation methods over the years, with the current methodology adopted in 2003. For a chronological summary of the history of the OTR, refer to *Overhead Transfer Rate (OTR)—Timeline* at *https://www.ncua.gov/About/Documents/Budget/Misc%20Documents/overhead-transfer-rate-chronology.pdf.* For a detailed explanation of the current methodology, refer to **Federal Register**—*NCUA Request for Comment Regarding Overhead Transfer Rate Methodology* at *https://www.federalregister.gov/documents/2016/01/27/2016-01626/request-for-comment-regarding-overhead-transfer-rate-methodology.*

II. Legal Authority Comments and Responses

The Board detailed the legal parameters within which it must fund the NCUA Operating Budget in the January 2016 notice and request for comment.[7] While the Board did not expressly solicit comments on said authorities, a number of comments addressed NCUA's legal authority. Below the Board restates the legal parameters outlined in the January 2016 notice. Within these parameters, NCUA has developed a new OTR methodology proposed in this publication that continues to ensure application that is fair to both federal credit unions and federally insured state-chartered credit unions, and that is consistent across all of NCUA's cost centers.

a. Legal Authority

NCUA charters, regulates and insures shares in federal credit unions and insures shares and deposits in federally insured state-chartered credit unions. To cover expenses related to its statutory mission, the Board adopts an Operating Budget in the fall of each year. The Act authorizes two primary sources to fund the Operating Budget: (1) Requisitions from the Share Insurance Fund ''for such administrative and other expenses incurred in carrying out the purposes of

[1] 81 FR 4804 (Jan. 27, 2016).

[2] *https://www.ncua.gov/About/Pages/Mission-and-Vision.aspx.*

[3] In coordination with State Supervisory Authorities with respect to federally insured state-chartered credit unions.

[4] Some costs are directly charged to the Share Insurance Fund or the Temporary Corporate Credit Union Stabilization Fund when appropriate to do so. For example, costs for training and equipment provided to State Supervisory Authorities are directly charged to the Share Insurance Fund.

[5] Other sources of funding for the Operating Budget include interest income, funds from publication sales, parking fee income, and rental income.

[6] *http://www.gao.gov/assets/210/203181.pdf.*

[7] 81 FR 4804 (Jan. 27, 2016).

[Title II of the Act] as [the Board] may determine to be proper''; [8] and (2) ''fees and assessments (including income earned on insurance deposits) levied on insured credit unions under [the Act].'' [9] Among the fees levied under the Act are annual Operating Fees, which are required for federal credit unions under 12 U.S.C. 1755 ''and may be expended by the Board to defray the expenses incurred in carrying out the provisions of [the Act,] including the examination and supervision of [federal credit unions].'' Taken together, these dual primary funding authorities effectively require the Board to determine which expenses are appropriately paid from each source while giving the Board broad discretion in allocating these expenses.

To allocate agency expenses between these two primary funding sources, NCUA uses the OTR. The OTR represents the formula NCUA uses to allocate insurance-related expenses to the Share Insurance Fund under Title II. Almost all other operating expenses are collected through annual Operating Fees paid by federal credit unions.[10] Two statutory provisions directly limit the Board's discretion with respect to Share Insurance Fund requisitions for NCUA's Operating Budget and, hence, the OTR. First, expenses funded from the Share Insurance Fund must carry out the purposes of Title II of the Act, which relate to share insurance.[11] Second, NCUA may not fund its entire Operating Budget through charges to the Share Insurance Fund.[12] NCUA has not imposed additional policy or regulatory limitations on its discretion for determining the OTR. If NCUA's OTR methodology were challenged, the court would uphold NCUA's methodology unless it were shown to be arbitrary or capricious, contrary to law, or unsupported by statutory authority under the Administrative Procedure Act (APA).[13] The Board believes the existing OTR and this proposal are fully consistent with the APA and all other applicable law.[14]

b. Comments

In response to its initial OTR notice, NCUA received a variety of comments related to the legal authority to requisition funds from the Share Insurance Fund to cover a portion of the Operating Budget. Several commenters stated the agency does not have authority or discretion to establish and determine the OTR. Some commenters asserted that NCUA lacks the legal authority to use the Share Insurance Fund to cover costs of operating the agency. Other commenters claimed NCUA has only very narrow authority to allocate costs, has too broadly interpreted its authority, and may assign to the Share Insurance Fund only those costs directly associated with share insurance payments for failed or troubled credit unions. Some commenters insisted NCUA is required to fund the vast majority of the cost of operating the agency through Operating Fees charged to federal credit unions, claiming Congress intended that Operating Fees were to subsidize costs in managing risk to the Share Insurance Fund. Having considered these comments, NCUA maintains that a plain reading of the Act, as described in section II.a. above and in the January 2016 notice, supports the agency's legal authority and broad discretion in allocating operating costs.

Various commenters disagreed with the agency's legal analysis and argued that some combination of 12 U.S.C. 1781(b)(1), 1782(a)(5), and 1790 also limit NCUA's requisition of funds from the Share Insurance Fund for the Operating Budget. Several commenters went further and argued that Title II's legislative history indicates the savings from NCUA's reliance on Title I and State Supervisory Authority examinations and reports should accrue to the benefit of the Share Insurance Fund. The Act's plain language does not require an analysis of the legislative history.[15] Even if legislative history was applicable in this case, the plain reading of the Act is consistent with the legislative history and does not support commenters' interpretation that Congress intended costs savings provisions to only accrue to the Share Insurance Fund as discussed below.

Multiple commenters stated that the plain language of the Act requires the Board to structure examinations and Call Reports originally required under Title I so they may be used for Title II share insurance purposes.[16] These commenters similarly stated that the Act places requirements on NCUA to use state regulator examinations and reports to the maximum extent feasible.[17] In response, the Board notes that Title II, in 12 U.S.C. 1781(b)(2), authorizes examinations as needed for the protection of the Share Insurance Fund and other credit unions in addition to those permitted under Title I, recognizing that the scope and timing of Title I examinations does not necessarily satisfy share insurance needs under Title II. Regardless of the parsing of the various statutory provisions on this point, the Board is careful to build efficiencies wherever reasonable in light of NCUA's dual roles as (1) charterer and prudential regulator of federal credit unions and (2) insurer of federal credit unions and federally insured state-chartered credit unions. Efficiencies gained from NCUA's dual role provide cost savings and help avoid subjecting credit unions to the burden of redundant examinations. Further, the Act's provisions on cost savings do not prohibit NCUA from allocating insurance-related operating expenses to the Share Insurance Fund through the OTR under 12 U.S.C. 1783(a). Specifically, 12 U.S.C. 1781(b)(1) requires NCUA to adjust the way it conducts examinations of federal credit unions so they may be ''utilized for share insurance purposes.'' This provision does result in cost savings. However, it does not preclude NCUA from allocating the costs of the ''share insurance purposes'' portion of federal credit union examinations to the Share Insurance Fund.[18] The Board thus disagrees with commenters that argued that the Act requires the cost-savings of NCUA's dual roles to accrue specifically to the Share Insurance Fund.

While the Board did not cite 12 U.S.C. 1790 as an additional limitation in its earlier notice, the Board agrees with commenters stating that this provision should inform NCUA's interpretation of Title II so that it consciously avoids discrimination against federally insured

[8] 12 U.S.C. 1783(a).

[9] 12 U.S.C. 1766(j)(3). Other sources of income for the Operating Budget include interest income, funds from publication sales, parking fee income, and rental income.

[10] Annual Operating Fees must ''be determined according to a schedule, or schedules, or other method determined by the NCUA Board to be appropriate, which gives due consideration to the expenses of the [NCUA] in carrying out its responsibilities under the [Act] and to the ability of [FCUs] to pay the fee.'' 1755(b). The NCUA Board's methodology for determining the aggregate amount of Operating Fees was discussed in a separate **Federal Register** publication.

[11] 12 U.S.C. 1783(a).

[12] The Act in 12 U.S.C. 1755(a) states, ''[i]n accordance with rules prescribed by the Board, each [federal credit union] shall pay to the [NCUA] an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.'' See also 12 U.S.C. 1766(j)(3).

[13] 5 U.S.C. 706(2).

[14] *See, e.g., Motor Vehicle Mfrs. Ass'n of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29 (1983).

[15] *See, e.g., Barnhart* v. *Sigmon Coal Co.,* 534 U.S. 438, 450 ((2002).

[16] 12 U.S.C. 1781(b)(1), 1782(a)(5).

[17] *Id.*

[18] With respect to call reports and other ongoing reports submitted by federally insured credit unions, 12 U.S.C. 1782(a)(5) is also a cost savings provision but does not preclude allocating insurance-related costs of the applicable data collections to the Share Insurance Fund.

state-chartered credit unions to the benefit of federal credit unions.[19] However, the Board does not believe that either the current or the proposed OTR process discriminates against federally insured state-chartered credit unions or federal credit unions to the benefit of the other.

As background, all federally insured credit unions are subject to the same requirements for funding the Share Insurance Fund. Specifically, § 1782(c)(1)(A)(i) requires that ''[e]ach insured credit union shall pay to and maintain with the [Share Insurance Fund] a deposit in an amount equaling 1 per centum of the credit union's insured shares.'' Section 1782(c)(2)(A) requires that ''[e]ach insured credit union shall, at such times as the Board prescribes (but not more than twice in any calendar year), pay to the Fund a premium charge for insurance in an amount stated as a percentage of insured shares (which shall be the same for all insured credit unions).'' Thus, in funding the Share Insurance Fund, federal credit unions and federally insured state-chartered credit unions are not treated any differently. Similarly, the requisitions from the Share Insurance Fund used to fund the insurance-related expenses of NCUA's Operating Budget under § 1783(a) do not distinguish between federal credit unions and federally insured state-chartered credit unions.

As for the OTR methodology and whether it complies with § 1790, the OTR methodology only considers the type of activity (*i.e.* insurance-related or not) and treats the expenses related to that activity the same regardless of the type of charter to which the activity applies. Specifically, both the existing and proposed OTR methodologies provide that all insurance-related expenses are funded from the Share Insurance Fund, regardless of charter type.

The Act clearly permits expenses related to insurance to be funded by the Share Insurance Fund regardless of charter. Specifically, 12 U.S.C. 1783(a) expressly allows expenses ''incurred in carrying out the purposes of [Title II]'' to be allocated to the Share Insurance Fund. The costs NCUA incurs in safeguarding the Share Insurance Fund relate to the risks in federal credit unions and federally insured state-chartered credit unions. The Act provides the Board with a number of specific authorities that relate to costs NCUA incurs in carrying out its obligations under Title II. For instance, Title II of the Act authorizes the Board ''to appoint examiners who shall have the power, on its behalf, to examine any insured credit union . . . whenever in the judgment of the Board an examination is necessary to determine the condition of any such credit union for insurance purposes.'' [20] Further, Title II authorizes the Board to implement regulations applicable to all insured credit unions to address risk to the Share Insurance Fund. Title II states the Board may ''prescribe such rules and regulations as it may deem necessary and appropriate to carry out the provisions of this subchapter.'' [21] Title II also grants the Board the following additional authorities relevant to agency operating costs:

- ''Appoint such officers and employees as are not otherwise provided for in this chapter;'' [22]
- ''employ experts and consultants or organizations thereof;'' [23]
- ''prescribe the manner in which its general business may be conducted and the privileges granted to it by law may be exercised and enjoyed;'' [24]
- ''exercise all powers specifically granted by the provisions of this subchapter and such incidental powers as shall be necessary to carry out the power so granted;'' [25] and
- ''make examinations of and require information and reports from insured credit unions, as provided in this subchapter.'' [26]

The Board concludes that these authorities taken together provide NCUA as insurer with broad discretion to impose regulations on and examine all insured credit unions. In addition, the cost of the agency activities associated with exercising these and other accompanying authorities can properly be considered costs of carrying out Title II of the Act.[27]

Finally, a number of commenters argued that the OTR methodology and/or calculations either should or must go through full APA notice and comment rulemaking. The APA does not require notice and comment for the OTR methodology. The legal analysis of NCUA's Office of General Counsel on the applicability of the notice and comment provisions of the APA to the OTR methodology is summarized in the January 2016 OTR notice [28] and articulated more fully in a legal opinion posted on NCUA's Web site.[29] In soliciting comment on the OTR through the **Federal Register** NCUA has gone, and continues to go, beyond its APA obligations.

III. Current OTR Methodology and Process Comments and Responses

a. Formula Driven or Set at the Discretion of the Board

The majority of commenters expressed support for NCUA's continued use of a formula to determine the OTR. The Board agrees NCUA should continue to use a formula to determine the OTR. Use of a well-designed and comprehensive formula represents a good faith effort to consider all of the agency's costs relative to how NCUA is carrying out its various responsibilities. A formula also helps ensure costs assigned to the OTR relate to agency activities to carry out Title II responsibilities. NCUA's goal in using a formula-driven OTR methodology is to provide a comprehensive, fair, and equitable allocation of costs within a framework that can be administered at a relatively low cost. Though it is formula driven, the Board can adjust the methodology at any time to ensure it continues to reflect the most equitable and suitable approach to allocating costs.

However, five commenters favored setting the OTR at a fixed 50 percent of

[19] 12 U.S.C. 1790 (''It is not the purpose of this subchapter to discriminate in any manner against State-chartered credit unions and in favor of Federal credit unions, but it is the purpose of this subchapter to provide all credit unions with the same opportunity to obtain and enjoy the benefits of this subchapter.'').

[20] 12 U.S.C. 1784(a).

[21] 12 U.S.C. 1789(a)(11).

[22] 12 U.S.C. 1789(a)(4).

[23] 12 U.S.C. 1789(a)(5).

[24] 12 U.S.C. 1789(a)(6).

[25] 12 U.S.C. 1789(a)(7).

[26] 12 U.S.C. 1789(a)(8).

[27] For example, Title II specifically addresses a broad range of standards for all insured credit unions, including standards for insurance against burglary and defalcation, loss reserve requirements, investment limitations, ongoing reporting requirements (such as the Call Report), independent audits, accounting principles, national flood insurance program requirements, liquidity capacity, unsafe and unsound conditions or practices, security standards, recordkeeping, monetary transaction and recordkeeping and reporting, benefits to institution affiliated parties, capital standards, and approval of officials.

[28] 81 FR 4804 (Jan. 27, 2016) (''Since its inception, NCUA has taken the position that the OTR is not a legislative rule under the Administrative Procedure Act (APA) and is, therefore, exempt from notice and comment rulemaking processes. [ ] As such, NCUA has never used notice and comment rulemaking to establish either an individual determination of the OTR or the general methodology used to calculate the OTR. However, the OTR has been explained, discussed, and reviewed in various public records, including in annual Board Action Memorandums related to budget matters, independent evaluations, and other documents available in public records and on NCUA's Web site.[ ] Beyond its APA obligations, the Board has chosen to solicit public comments on the OTR processes and methodologies through this **Federal Register** publication.'').

[29] NCUA's legal analysis with respect to the OTR and APA process is available at the following Web page: *https://www.ncua.gov/Legal/Documents/Opinion/OL2015-0818.pdf.*

the Operating Budget. Commenters that supported setting the OTR at 50 percent indicated that it is easily understandable, more in line with the dual functions of NCUA as regulator and insurer, and that the OTR was set at 50 percent for many years. The Board does not believe it is transparent or appropriate to set the OTR at any level, such as the 50 percent recommended by commenters, without a reasoned basis to demonstrate that level of agency operating costs are properly allocated to Title II activities.[30] However, the Board agrees that the OTR methodology can be simplified and maintain a sufficient degree of comprehensiveness to ensure it is equitable. Such a simplification should improve understanding of the OTR and reduce administrative costs. For a discussion of how the Board proposes to simplify the OTR methodology, see section IV.

b. Delegation of the OTR Calculation to NCUA Staff

Ten commenters objected to the Board's delegation of the OTR calculation to NCUA staff. They argued that by doing so the Board abdicated its oversight and discretion over the OTR and that it will result in reduced transparency. During the November 29, 2015, Board meeting, the Board approved the delegation of authority to administer the Board approved OTR methodology to the Director of the Office of Examination and Insurance (E&I).[31]

Delegating the ministerial application of the Board approved OTR methodology does not mean the Board has abdicated its oversight and discretion for the OTR. With limited exceptions not at play here, the Act permits the Board to ''delegate to any officer or employee of the Administration such of its functions as it deems appropriate.'' [32] Further, the current delegation to staff to administer the OTR does not provide staff with the power to change the methodology for calculating the OTR. Rather it mirrors the typical organizational separation of duties where the board sets policy and staff implements the policy. The Board retains approval authority over the methodology that is used to calculate the OTR; only the Board can change the OTR methodology or use its discretion to change the OTR from the calculated result if circumstances so warranted. However, having the OTR set by a Board approved formula, instead of an explicit Board vote each year, helps avoid any perception that the agency would casually override the calculation in setting the OTR. At any time, any Board member may request a Board vote be scheduled to change the OTR methodology, or to change the OTR from the calculated result.

The delegation has not resulted in a reduction in transparency. As was done prior to the delegation, each year staff submits a report to the Board on the results of the calculation and conducts a briefing at a public Board meeting. The materials supporting the OTR calculation and the result are provided as part of the public Board briefing and posted on the agency's Web site. The Board intends for this public reporting to continue. Further, the Board is committed to soliciting public input at least every three years on the OTR methodology, and any time a change to the methodology is considered.

c. Transparency

Nine commenters stated that the current OTR methodology is not sufficiently transparent. NCUA has made various efforts over the years to be transparent with respect to the OTR, and recently published extensive information about the OTR. The setting of the OTR has been briefed and acted on each year at a public Board meeting. The associated Board Action Memorandums, which are public records, fully detailed the calculation and included supporting materials. The current methodology was extensively reviewed at a public Board meeting when adopted in 2003. All related materials have been made a matter of public record and posted on NCUA's Web site. Numerous analyses, independent evaluations, and other documents are available in public records and on NCUA's Web site. To improve transparency further, the agency organized and posted a variety of new and historical materials on its Web site in 2015.[33] Additionally, the January 27, 2016, request for comment regarding the OTR methodology provided detailed explanations for the processes and methodology related to calculating the OTR. Although all information related to the OTR calculation is publicly available already, the Board acknowledges that an obstacle to transparency is the complexity of the methodology itself. In an effort to address the transparency concern, the Board is considering simplifying the OTR methodology. While still formula driven, the proposed changes to the methodology would provide for a simpler approach that remains comprehensive, fair, and equitable. The proposed changes to the methodology are described in detail in section IV of this document.

d. Definition of Insurance-Related Activities

NCUA's definition of insurance-related activities received the most comments. Of the 36 commenters on this topic, most disagree with the definition NCUA uses for insurance-related activities. Many commenters objected to equating ''safety and soundness'' with ''insurance-related,'' with some arguing that the charterer/prudential regulator cares about safety and soundness and it is therefore not the sole domain of the insurer. Commenters asserted the definition assumes that NCUA has no safety and soundness oversight in its role as regulator and charterer of federal credit unions. By doing so, commenters claim NCUA is shifting expenses that should fall under the operating fee paid by federal credit unions to the Share Insurance Fund.

NCUA recognizes the historical role of a charterer/prudential regulator involves enforcing laws and implementing public policy. Before the advent of federal deposit insurance, federal financial institution regulators were concerned with protecting the stability of the financial system by ''regulating'' it. Thus, financial institution examinations focused on ensuring (1) statutes and regulations were followed to protect consumers, and (2) institutions were viable to protect consumer deposits, preserve access to financial services, and safeguard the stability of the economy. Though not responsible for the financial liability that comes with the role of insurer, prudential regulators are concerned with potential threats to the viability of their financial institutions to protect consumers and their jurisdiction's economy. This focus on viability benefits the insurer, whose primary role is to protect depositors and the taxpayer and contribute to the stability of the financial system.

NCUA has a unique dual role in that it serves as both the regulator of federal credit unions and the insurer of all federally insured credit unions.[34]

[30] *See* 12 U.S.C. 1783(a).

[31] NCUA Board Action Bulletin found at the following web address: *https://www.ncua.gov/About/Pages/board-actions/bulletins/2015/november/BAB20151119.aspx.*

[32] 12 U.S.C. 1789(a)(10); *see also* 1766(d).

[33] Materials related to the OTR can be found at *www.ncua.gov/About/Pages/budget-strategic-planning/supplementary-materials.aspx.*

[34] The Office of the Comptroller of the Currency (OCC) charters, regulates, and supervises all national banks and federal savings associations as well as federal branches and agencies of foreign banks. On its Web site, the OCC lists its mission as ensuring that national banks and federal savings

Continued

Congress established the Share Insurance Fund and assigned its administration to the Board.[35] This arrangement has a variety of benefits. A regulator/supervisor with insurance responsibility creates a strong alignment of incentives in preserving safety and soundness, thereby managing risk to the Share Insurance Fund. The appropriate combination of functions reduces the likelihood that a regulator would act without adequate regard for the insurance implications. It also generally avoids additional and duplicative oversight costs, and the corresponding burden on insured institutions of separate requirements and supervision from a different regulator and insurer.

Given its multiple roles, NCUA appropriately allocates costs associated with activities connected to each role. Various provisions of the Act, as noted earlier, govern or inform this allocation. Thus, NCUA currently categorizes those activities designed to manage risk to the Share Insurance Fund as ''insurance-related.'' This includes activities designed to enforce regulations NCUA adopts to carry out the purpose of Title II (Share Insurance) as well as related examination and supervision activities.[36] NCUA's categorization focuses on the primary motivation for the regulation or examination and supervision activity. The motivation for insurance-related regulations and examination activities is based on the nature of the threat to the viability of the institution, and therefore potential losses to the Share Insurance Fund. The insurance-related definition excludes procedures that assess compliance with other regulations. Consumer protection and other laws and regulations (such as field of membership rules) designed to otherwise govern how credit unions operate, and related examination activities, are not primarily intended to reduce the potential for losses to the Share Insurance Fund. Moreover, while systemic and egregious violations of such laws could result in material fines to the institution, such occasions are very infrequent and rarely result in the failure of the institution or losses to the Share Insurance Fund.

Thus, NCUA currently allocates costs associated with regulating and examining the safety and soundness of insured institutions as insurance-related. Worthy of note, Congress uses ''safety and soundness'' and related terminology in the Act.[37] There are two subjects in Title I containing safety and soundness terminology: the interest rate ceiling for federal credit unions (12 U.S.C. 1757(5)(A)(vi)(I)) and provisions regarding multiple common bond groups (12 U.S.C. 1759(d) and 12 U.S.C. 1759(f)). The current safety and soundness language applying to these two subjects in Title I was added after Title II was enacted. There are 19 references to safety and soundness in Title II. These provisions cover a range of subjects.[38] In particular, NCUA's various enforcement authorities for violations of laws or regulations and unsafe or unsound conditions or practices are contained in Title II. Thus, most of Congress' focus on safety and soundness in the Act is in the context of share insurance.

However, NCUA acknowledges that safety and soundness is not the sole domain of the insurer; prudential regulators have various responsibilities with respect to the ''safety and soundness'' of institutions they oversee. In some respects this is recognized in the current OTR formula through the ''Imputed SSA Value.'' To better reflect that the prudential regulator and insurer both have responsibilities for safety and soundness, the Board is considering adjusting the OTR methodology so safety and soundness is not accounted for as the primary domain of the insurer. For more information on the proposed change to the OTR methodology, see section IV.

One commenter stated that routine examinations of all insured credit unions should be paid through Operating Fees. Another commenter asserted that the OTR should only be used for examinations of federally insured state-chartered credit unions and examinations of troubled federal credit unions. These recommendations assume that as insurer, NCUA takes only a reactive approach to managing risk to the Share Insurance Fund.

The Board notes that NCUA's role as insurer is best fulfilled by a proactive approach to preventing losses, not just addressing troubled or failed institutions. Since the implementation of federal share insurance in 1970, the Board has instituted a more proactive examination and supervision program geared toward safety and soundness to better manage risk to the Share Insurance Fund. Additionally, as credit unions have become larger and more complex, the risks to the Share Insurance Fund have changed, with NCUA making corresponding adaptions to its operations. In 2002, the Board strengthened its commitment to fulfilling NCUA's role as insurer by implementing the Risk-Focused Examination Program. As recently as 2016, the Board made the examination program even more risk-based by adopting an extended examination cycle for healthy, well-run credit unions. These programs base examination scope and timing largely on the risks an institution poses to the Share Insurance Fund. Further, the objective of the risk-focused examination is to enable NCUA to identify and address risks before they become a major problem. All of these changes have resulted in an increase in the agency's insurance-related activities.

The Act and NCUA Regulations have also evolved, resulting in more emphasis on safeguarding the Share Insurance Fund. For example:

1. The Credit Union Membership Access Act was enacted into law in 1998.[39] This law resulted in new obligations on credit unions and NCUA, such as prompt corrective action, designed to protect the Share Insurance Fund.

associations operate in a safe and sound manner, provide fair access to financial services, treat customers fairly, and comply with applicable laws and regulations. Similarly, the Board of Governors of the Federal Reserve System has supervisory and regulatory authority over a wide range of financial institutions, including state-chartered banks that are members of the Federal Reserve System, bank holding companies, thrift holding companies and foreign banking organizations that have a branch, agency, a commercial lending company subsidiary or a bank subsidiary in the United States. On its Web site, the Federal Reserve states its mission is to provide the nation with a safer, more flexible, and more stable monetary and financial system. One of its four stated general duties is supervising and regulating banking institutions to ensure the safety and soundness of the nation's banking and financial system and to protect the credit rights of consumers. On its Web site, the Federal Deposit Insurance Corporation states its mission is to maintain stability and public confidence in the nation's financial system by insuring deposits, examining and supervising financial institutions for safety and soundness and consumer protection, making large and complex financial institutions resolvable, and managing receiverships.

[35] 12 U.S.C. 1782, 1783.

[36] As noted in the Legal Authority section, NCUA has the authority to promulgate rules and regulations to carry out the purpose of Title II—Share Insurance. Accordingly, the NCUA Board has approved rules and regulations that specifically address credit union activities that pose risk to the Share Insurance Fund. NCUA has mapped all examination related rules and regulations to one of two categories: insurance regulatory related, or non-insurance or consumer regulatory related. This regulatory mapping provides the basis for determining how examination time is reported for use in the current OTR methodology. The mapping is discussed in detail in the 2013 independent study by PwC and in NCUA's January 2016 request for comment.

[37] ''Safe and sound,'' ''safety and soundness,'' and ''unsafe or unsound'' are the terminology encompassing safety and soundness found in the Act.

[38] See 12 U.S.C. 1781(c)(2), 1782(a)(6)(B), 1786(b), 1786(e), 1786(f), 1786(g), 1786(k)(2), 1786(r), 1786(s), and 1790d(h).

[39] Information about the Credit Union Membership Access Act is contained within NCUA Letter to Credit Unions 98–CU–16 located at the following web address: *https://www.ncua.gov/Resources/Documents/LCU1998-16.pdf.*

2. During the aftermath of the financial crisis, the Board strengthened critical safety and soundness rules, such as interest rate risk and liquidity management standards.

3. NCUA also has been providing regulatory relief. New authorities and less prescriptive, more principles-based rules have helped to reduce compliance burdens and provide credit unions with more authority to serve members and manage risk. They result in examiners devoting more time to ensuring safety and soundness through the examination process rather than relying on regulatory limits.

Under this proactive approach, the Board's primary motivation for many of the agency's current regulations and the majority of the examination program is to manage risk to the Share Insurance Fund.

The Board acknowledges there is not always a clear separation between the role of a prudential regulator concerned with enforcing laws and implementing public policy and that of an insurer. For example, NCUA relies, to the extent feasible, on the examination work performed by state regulators to manage risk to the Share Insurance Fund posed by federally insured state-chartered credit unions. This results in some cost savings in the NCUA Operating Budget. Since 2004, the value of the insurance-related work conducted by state regulators and relied on by NCUA has been reflected in the OTR methodology as the ''Imputed SSA Value.'' To ensure equitable treatment, the Imputed SSA Value is calculated on the same cost basis as if NCUA had to conduct the work itself.[40] The current methodology applies the same approach and definition of insurance-related examination activities to examinations of federally insured state-chartered credit unions as for federal credit unions. The Imputed SSA Value has the effect of reducing the OTR, thereby taking into account the fact that all insured credit unions benefit from the insurance-related examination costs of state regulators borne by state-chartered credit unions.

The Board recognizes that another plausible approach to accounting for the related missions of charterer/prudential regulator and insurer is to employ an alternating or partnership framework within the OTR methodology. This would simplify the OTR methodology and avoid having to delineate safety and soundness as the primary domain of the insurer. The concept of an alternating or partnership framework being applied to the OTR methodology is described in detail in section IV of this document.

e. State Regulator Costs

Some commenters asserted that because NCUA equates safety and soundness with insurance-related activities, the OTR methodology is not fair and equitable as state regulators also examine federally insured state-chartered credit unions for safety and soundness. As a result, some commenters contended federally insured state-chartered credit unions are charged twice for safety and soundness examinations; once by their state regulator via an operating fee and then by NCUA via the OTR. Further, some commenters claimed that federally insured state-chartered credit unions are disadvantaged when the OTR rises due to increased NCUA examination time allocated to insurance, because the NCUA operating fee paid by federal credit unions declines.

NCUA appreciates the work state regulators do in contributing to the safety and soundness of the credit union system. The agency will continue to partner and coordinate closely with state regulators in this regard. It is important to note that ultimately NCUA is accountable for carrying out the purpose of Title II of the Act and managing risk to the Share Insurance Fund. The extent state regulators examine for safety and soundness is the choice of state governments. This choice, along with the adequacy of the examination, affects the extent to which it is feasible for NCUA to rely on these examination reports to meet its Title II responsibilities. State governments also choose the extent to which they rely on the work of NCUA in its role as insurer to reduce overall state costs and burden.

State-chartered credit unions are not charged twice as a result of state regulators also examining for safety and soundness. The extent to which state regulators examine for safety and soundness in a manner that can be relied on by NCUA reduces the overall agency costs to which the OTR is applied, benefiting all insured credit unions. Conversely, NCUA's involvement in developing reporting and examination systems for all insured credit unions, publishing guidance, training and equipping most state examiners, and participating in the examination of federally insured state-chartered credit unions reduces overall state regulator costs.[41] As discussed above, the current OTR methodology takes into account via the Imputed SSA Value the insurance-related work conducted by state regulators and relied on by NCUA. In addition, the Imputed SSA Value is calculated using the same examination time allocation for federal credit unions. Thus, when more of the agency's examination time is dedicated to insurance-related areas, the Imputed SSA Value also increases. The Imputed SSA Value has the effect of reducing the OTR (and conversely increasing the operating fee paid by federal credit unions) to the benefit of state-chartered credit unions. This provision helps ensure the current OTR methodology is fair and equitable.[42]

Some commenters suggested that if the OTR continued to define all safety and soundness activities as insurance-related, NCUA should use each state regulator's actual costs instead of an imputed value. Others argued NCUA should pay the state governments for their actual costs instead of merely reducing the OTR.

NCUA notes that it is neither feasible nor appropriate to use the actual state regulator costs in determining the OTR. To ensure the methodology is fair and equitable across all federally insured institutions, the Imputed SSA Value is intentionally designed to reflect the replacement cost to NCUA if the agency had to do the insurance-related work it relies on the state regulators to conduct. The cost structure for state regulators can vary widely and include non-germane and potentially inordinate costs. Also, it is not feasible to obtain reliable and comprehensive information

[40] The Imputed SSA Value for 2017 is $50.8 million.

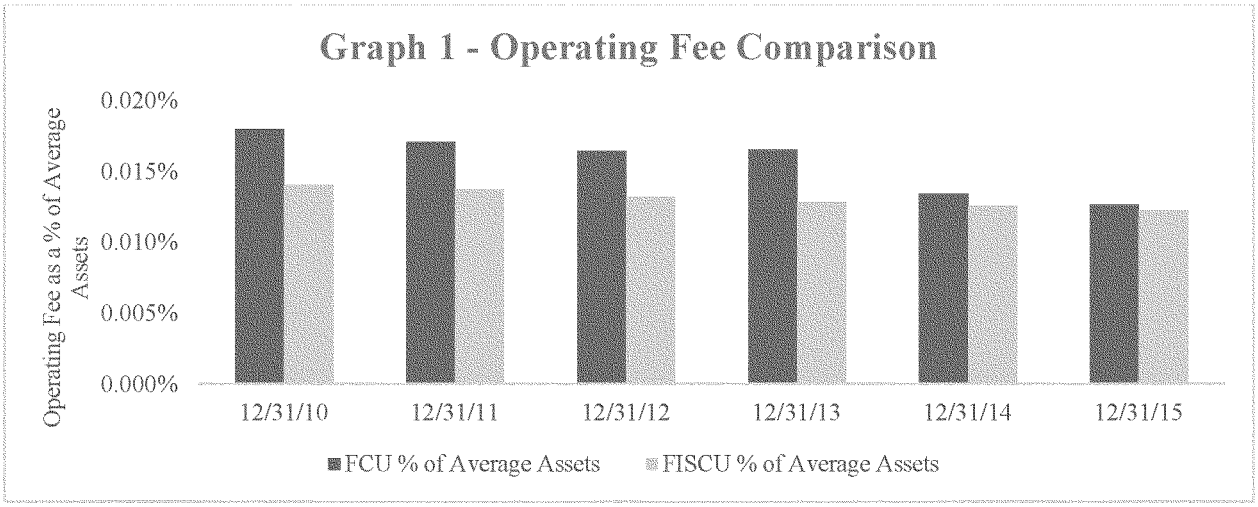
[41] NCUA budgeted to spend over 150,000 hours participating in the examination and supervision of federally insured state-chartered credit unions in 2017. To conduct this additional work would require state regulators to add an estimated 175 staff at a cost of up to $35 million. Most state regulators participate in NCUA's examiner training programs, use the agency's examination and Call Report systems, and benefit from the agency's exam techniques and supervisory guidance. State regulators would have to individually or collectively develop and administer these functions and systems if NCUA did not provide them. For context, NCUA's 2017 budget included the following for units associated with these functions and systems: $10.5 million for the Division of Training and Development; $16.4 million for the Office of the Chief Information Officer's information technology operations; and $12.3 million for the Office of Examination and Insurance. Also, NCUA's 2017 capital budget includes $10.4 million to support the Enterprise System Modernization program; much of this program involves modernization of systems that directly or indirectly support supervising credit unions. Additionally, in 2017 NCUA budgeted $1.4 million for training of state examiners and $162,480 in computer lease expense for equipment provided to state regulators.

[42] Overhead Transfer Rate Review, PriceWaterhouseCoopers, Section 1.4.3 (January 20, 2011) (Based on PwC's review, there was no reasonable basis to conclude that the OTR methodology ex-ante and for reasons beyond the control of credit unions, favours or disadvantages any one type of credit unions (*i.e.* federal versus state chartered) over another.)

about the relevant cost of each state regulator. NCUA has no authority to compel states to provide this information, nor to maintain records in such a way as to ensure proper allocation of germane costs.

As part of the process of evaluating the suggestion to use actual state regulator costs, NCUA attempted to obtain and review the costs of state regulators and their methodologies for annual and/or examination fees for state-chartered credit unions. This included determining how costs are allocated to the credit union specific activities for state regulators housed within state offices with broader responsibilities.[43] NCUA staff first reviewed publicly available information with limited success. NCUA also sent letters to the state regulators to request details on fee structures, costs, and allocation factors for credit union specific activities. The information request did not result in sufficiently comprehensive information upon which to draw any reliable conclusions.[44]

Based on Call Report data, NCUA did compare the total Operating Fees as a percent of average assets paid by federal credit unions to those reported by federally insured state-chartered credit unions. Though this comparison has some limitations, the trends in Graph 1 below show that Operating Fees recorded by federal credit unions and federally insured state-chartered credit unions are comparable in aggregate.



Further, federal credit unions continue to bear the majority of NCUA's operating costs. For NCUA's 2017 Operating Budget, federal credit unions cover 67 percent of the total Operating Budget through the operating fee and their proportional share of the OTR.

f. Regulation Mapping[45]

NCUA has mapped all examination-related rules and regulations to one of two categories: Insurance regulatory related, or non-insurance and consumer regulatory related. A third party has reviewed the regulatory mapping.[46] NCUA reviews the regulatory mapping prior to the beginning of each examination time survey cycle for any necessary updates.[47] A detailed review was completed again for 2017 that resulted in minor adjustments to classifications. For the full regulatory mapping, see the 2017 Mapping of NCUA Rules and Regulations document posted on NCUA's public Web site at *https://www.ncua.gov/About/Documents/mapping-ncua-regulations-2017.pdf.*

Since NCUA equates safety and soundness with the term insurance-related in the current OTR methodology, commenters argued that the mapping of NCUA's rules and regulations is faulty. Some commenters asserted that classifying NCUA rules as insurance-related is flawed because NCUA as charterer/prudential regulator is charged with ensuring compliance with all the provisions contained within the rules and regulations.

As noted in the Legal Analysis section above, the Board has the authority to promulgate rules and regulations to carry out the provisions of Title II (Share Insurance) of the Act, as well as examine credit unions for share insurance purposes.[48] Accordingly, the Board has approved rules and regulations that specifically address safety and soundness with the intent to protect the Share Insurance Fund. As such, the current OTR methodology accounts for examination and supervision activities for insurance-related regulations as an insurance cost.

As noted above, the Board recognizes that another plausible approach to accounting for the related missions of charterer/prudential regulator and insurer is to employ an alternating or partnership framework within the OTR methodology. This would simplify the OTR methodology in part by avoiding having to map regulations to a specific role as it relates to federal credit unions. The concept of an alternating or partnership framework being applied to

[43] Based on the responses received from the state regulators, many state credit union programs are divisions contained within a larger office with funds co-mingled with other programs. The state regulators that responded and that do not separate funds for credit unions from other financial institutions supervised generally either do not allocate expenses or did not provide their allocation methodology.

[44] In total, 27 state regulators responded to varying degrees. These state regulators provided as much of the requested information as they could, given limitations they faced.

[45] As part of the current OTR methodology, the agency maps NCUA examination activities related to specific regulations based on the primary purpose of the regulation—whether it is for carrying out the purpose of Title II (insurance-related) or part of NCUA's responsibility as charterer or prudential regulator. For details regarding the regulation mapping, see Appendix A of the January 27, 2016 request for comment.

[46] PwC National Credit Union Administration (NCUA) Analysis of Examination Time Survey (ETS) Modifications—October 2, 2013: *https://www.ncua.gov/About/Documents/Budget/2013/2013ETSAnalysis.pdf.*

[47] The examiner time survey is performed annually and is used to determine the percentage of the workload budget relates to regulatory and insurance-related tasks for federal examinations and supervision contacts.

[48] 12 U.S.C. 1789(a).

the OTR methodology is described in detail in section IV of this document.

g. Other Methodological Aspects of the OTR

NCUA received 23 comments suggesting various other changes to the current OTR process. The areas of the calculation receiving comments were the examiner time survey, the allocation factors for various NCUA central offices, and the use of insured shares in the calculation.

• Examiner time survey: [49] Commenters generally agreed with using a time survey in allocating the cost of federal credit union examination and supervision. However, some commenters suggested NCUA conduct a time survey during all examinations and supervision contacts instead of on a statistically valid sample basis. Some commenters suggested having state regulators complete the examiner time survey as well.

It is not necessary to have 100 percent coverage of all examination and supervision contacts to form a statistically valid basis for the survey. A complete census of all federal credit union examinations and supervision contacts would result in additional agency costs—all staff would have to be trained annually and all examinations and supervision contact hours would need to be increased for the time necessary to complete the survey.[50] Moreover, the survey is not pertinent to NCUA's work in federally insured state-chartered credit unions given NCUA is only functioning in its capacity as insurer.[51] The benefits of any small increases in precision would be outweighed by the corresponding costs. With respect to state regulator examinations, the agency has no authority to require state regulators to complete a time survey, and it would be challenging to ensure uniformity in how their time is reported. The proposed changes to the OTR methodology discussed in section IV would eliminate the need for an examiner time survey, resulting in additional cost savings.[52]

• Allocation factors for various NCUA central offices: Some commenters stated the allocation of costs for NCUA's non-field offices are not based on standard or consistent criteria. Overall, NCUA agrees that improvements can be made in allocation methods involving the non-field cost centers, and is addressing this in the proposed changes to the OTR methodology. Some noted that the Office of National Examinations and Supervision (ONES) costs cannot be 100 percent safety and soundness as it examines natural person credit unions with assets over $10 billion and, therefore, has regulatory responsibility. Other commenters noted ONES is also responsible for reviewing Bank Secrecy Act compliance for the corporate credit unions it supervises, suggesting some non-insurance time is spent supervising them. NCUA agrees that ONES time is not 100 percent insurance related and this issue was addressed in the 2017 OTR calculation. Other commenters questioned why the Office of Small Credit Union Initiatives and the Office of Consumer Financial Protection and Access vary in their methodology for classifying time spent on field of membership expansion. NCUA agrees that there are differences in the time allocations and has developed a consistent standard for use in the proposed changes to the OTR methodology discussed in section IV.

• *Use of Insured Shares:* Two commenters recommended not using insured shares in the calculation of the OTR. The commenters suggested that time and resources spent in each charter type would be more appropriate. In developing the revised OTR methodology in 2003, one of the main goals of NCUA was to allocate costs as precisely as possible. For the current OTR methodology, it is necessary and appropriate to incorporate insured shares to ensure it is precise and equitable. Use of insured shares is consistent with the mutual nature of the Share Insurance Fund and part of the statutory scheme related to Share Insurance Fund deposits, premiums and dividends.[53] It also reflects the fundamental economics with respect to how the implicit costs of the OTR are borne by federal and state-chartered credit unions. Nevertheless, there are reasonable alternative approaches to calculating the OTR that do not involve use of insured shares. As discussed in section IV, the proposed changes to the OTR method eliminate the need for use of insured shares in the calculation.

IV. Details of Proposed OTR Methodology

The proposed simplification of the OTR formula is intended to facilitate greater understanding of the methodology, and will decrease the agency resources necessary to administer the OTR. The new approach is within NCUA's authority and, though simplified, would provide a sufficient level of precision with respect to the allocation of agency costs. The simplified formula applies the following underlying principles to the allocation of agency operating costs:

1. Time spent examining and supervising federal credit unions is allocated as 50 percent insurance related. The 50 percent allocation mathematically emulates an examination and supervision program design where NCUA would alternate examinations, and/or conduct joint examinations, between its insurance function and its prudential regulator function if they were separate units within NCUA. It reflects an equal sharing of supervisory responsibilities between NCUA's dual roles as charterer/prudential regulator and insurer given both roles have a vested interest in the safety and soundness of federal credit unions.[54] It is consistent with the alternating examinations FDIC and state regulators conduct for insured state-chartered banks as mandated by Congress. Further, it reflects that NCUA is responsible for managing risk to the Share Insurance Fund and therefore should not rely solely on examinations and supervision conducted by the prudential regulator.

2. All time and costs NCUA spends supervising or evaluating the risks posed by federally insured state-chartered credit unions or other entities NCUA does not charter or regulate (for example, third-party vendors and CUSOs) is allocated as 100 percent insurance related. NCUA does not charter state-chartered credit unions nor

[49] The current examiner time survey is discussed in detail in the Request for Comment Regarding Overhead Transfer Rate Methodology published in the **Federal Register** on January 27, 2016.

[50] Completing examination time surveys increases the time spent on each examination and supervision contact by an average of one hour. This equates to about 6,000 hours if survey data was collected at every onsite examination and supervision contact. Additionally, annual training would be required for all examiners and supervisory examiners. This would increase training hours for field staff by about 700 hours. The total additional time would be about 6,700 hours, approximately 6 additional employees.

[51] As required by law, NCUA does review compliance with the Bank Secrecy Act and the Flood Disaster Protection Act when it conducts an examination of a federally insured state-chartered credit union and the state regulator has chosen not to conduct the review. These situations are limited and the time associated with this activity would have an indiscernible effect on the OTR.

[52] Based on the most recent Examination Time Survey results, field staff time would be reduced by approximately 200 hours annually. Central office and regional office staff time devoted to operating, maintaining, and administering the Examination Time Survey and related processes would be reduced by approximately 150 hours annually.

[53] 12 U.S.C. 1782(c)(2) and (3).

[54] The insurer may evaluate compliance matters as part of a reciprocal arrangement with the prudential regulator in evaluating matters specific to insurance as part of the overall shared supervision of a credit union. A simplified assumption of equal sharing reflects the offsetting benefits for each role under a framework emulating an alternating examination program.

serve as their prudential regulator. NCUA's role with respect to federally insured state-chartered credit unions is as insurer. Therefore, all examination and supervision work and other agency costs attributable to insured state-chartered credit unions is allocated as 100 percent insurance related.

3. Time and costs related to NCUA's role as charterer and enforcer of consumer protection and other non-insurance based laws governing the operation of credit unions (like field of membership requirements) are allocated as 0 percent insurance related.[55] As the federal agency with the responsibility to charter federal credit unions and enforce non-insurance related laws governing how credit unions operate in the marketplace, NCUA resources allocated to these functions are properly assigned to its role as charterer/prudential regulator.

4. Time and costs related to NCUA's role in administering federal share insurance and the Share Insurance Fund are allocated as 100 percent insurance related. NCUA conducts liquidations of credit unions, insured share payouts, and other resolution activities in its role as insurer. Also, activities related to share insurance, such as answering consumer inquiries about insurance coverage, are a function of NCUA's role as insurer.

These four principles are applied to the activities and costs of the agency to arrive at the portion of the agency's Operating Budget to be charged to the Share Insurance Fund as discussed in detail below.

Step 1—Workload Program

Annually, NCUA develops a workload budget based on NCUA's examination and supervision program to carry out the agency's core mission. The workload budget reflects the amount of time necessary to examine and supervise federally insured credit unions, along with other related activities, and therefore the level of field staff needed to implement the exam program. Applying principles 1, 2, and 3 (those relevant to the workload budget) to the applicable elements of the workload budget results in a composite rate that reflects the portion of the agency's overall mission program activities that are insurance related. For illustrative purposes, Table 1 shows the application of the allocation principles to the 2017 workload budget.[56]

TABLE 1—ALLOCATION OF WORKLOAD HOURS[57]

Workload programs 2017 data	Budgeted workload hours (A)	Percent insurance related (B)	Insurance-related workload hours (A) × (B)	Allocation basis
Federal Credit Union Examination & Supervision.	498,159	50	249,080	Based on allocation principle 1 reflecting NCUA's roles as both prudential regulator and insurer.
State Credit Union Examination & Supervision.	167,414	100	167,414	Based on allocation principle 2 reflecting NCUA's role as insurer.
Consumer Compliance Reviews & Related Training.	20,000	0	0	Based on allocation principle 3 reflecting NCUA's role as prudential regulator.
Field of Membership & Chartering	500	0	0	Based on allocation principle 3 reflecting NCUA's role as prudential regulator.
CUSO & Third-party Vendor Reviews	5,576	100	5,576	Based on allocation principle 2 reflecting NCUA's role as insurer. Field staff time conducting reviews of CUSOs and third-party vendors—NCUA does not charter or regulate CUSOs and third-party vendors.
Total	691,649	N/A	422,070	
Total Insurance-Related Workload Hours to Total Workload Hours.			61%	Weighted average of field staff program time devoted to NCUA's role as insurer.

Step 2—Operating Budget

The Operating Budget represents the costs of the activities associated with achieving the strategic goals and objectives set forth in the NCUA Strategic Plan. The Operating Budget is based on agency priorities and initiatives that drive resulting resource needs and allocations. Information related to NCUA's budget process, including detailed information on the Board-approved 2017 Operating Budget, is available on the agency's Web site.[58]

The agency achieves its primary mission through the examination and supervision program. For the proposed formula, as applied to the 2017 Operating Budget, the percentage of insurance-related workload hours (61 percent) derived from Step 1 represents the main allocation factor used in Step 2 for the costs of the field offices (the Regions and ONES). A few agency offices have roles that are significantly distinct enough to warrant their own allocation factors, as discussed below. A weighted average allocation factor (60 percent) representing the aggregate budgets for the Regions, Ones, and the specific agency offices listed in Step 2 is applied to the central offices that design or oversee the examination and supervision program, or support the agency's overall operations. These costs in total make up NCUA's Operating Budget. Table 2 reflects the application

[55] This includes any reviews of credit unions focused solely on compliance, such as a fair lending exam. It does not include the more broadly based examinations and supervision contacts of federal credit unions covered by principle 1. It also does not include enforcing laws, like Prompt Corrective Action, that are part of share insurance under Title II as covered by principle 4.

[56] If the proposed change to the methodology is adopted by the Board, the calculation would apply to future workload and operating budgets. Thus, actual results may vary from those presented herein for illustrative purposes.

[57] Numbers may not reconcile exactly due to rounding.

[58] *https://www.ncua.gov/About/Pages/budget-strategic-planning/supplementary-materials.aspx.*

of the OTR allocation factors to the 2017 Operating Budget as an example.

TABLE 2—ALLOCATION OF NCUA OPERATING BUDGET [59]

Cost area (2017 data)	Operating budget $ millions (A)	Percent insurance related (B)	Operating cost to be borne by the share insurance fund $ millions (A) × (B)
Regions and ONES: The financial budget for the agency's five regional offices and ONES is allocated based on the weighted average of insurance-related activities calculated from the workload budget in Step 1 (using principles 1, 2, and 3). Resources in the regions and ONES execute NCUA's examination program. Thus, the budgeted costs related to these programs should receive the same allocation basis as the programs themselves	170.9	61	104.3
Asset Management Assistance Center: Manages liquidation payouts and assets acquired from liquidations on behalf of the Share Insurance Fund. Thus, the OTR allocation factor is based on principle 4 and allocated at 100 percent insurance related	7.4	100	7.4
Office of Consumer Financial Protection and Access Largely in NCUA's role as charterer and prudential regulator, this office is responsible for chartering and field-of-membership matters, low-income designations, bylaw amendments, consumer financial literacy efforts, consumer inquiries and complaints, consumer protection compliance, fair lending examinations, and related interagency coordination. These activities are allocated based on principle 3 as 0 percent insurance related. The office does some work with respect to federally insured state-chartered credit unions, including share insurance coverage matters, in NCUA's role as insurer; these activities are allocated based on principle 4 as 100 percent insurance related. The net of this combined activity results in an allocation factor of 13 percent insurance related. See discussion below for more details	9.9	13	1.3
Office of Small Credit Union Initiatives: Provides consulting and training services for small credit unions, both federal credit unions and federally insured state-chartered credit unions. Also processes grants and loans for federally insured credit unions. Principle 1 is applied to the office's work with federal credit unions and principle 2 is applied to the office's work with federally insured state-chartered credit unions. The net of this combined activity results in an allocation factor of 60 percent insurance related. See discussion below for more details	6.5	60	3.9
Subtotal: The 60 percent subtotal factor represents the dollar-weighted average of the above four cost centers (Regions and Ones, Asset Management Assistance Center, Office of Consumer Financial Protection and Access, and Office of Small Credit Union Initiatives) representing specific aspects of NCUA's mission	194.6	60	116.8
All Other Offices: This category includes the offices that design or oversee the agency's mission and its related offices, or provide necessary support to mission offices or the entire agency. As such, the proportion of insurance-related activities for these offices correspond to that of the mission offices. Therefore, these office costs are allocated based on the weighted average of insurance-related activities calculated in the subtotal above	103.6	60	62.2
Total	298.2	.....	179.0

Regional Offices and ONES

The financial budget for the agency's five regional offices and ONES is allocated based on the weighted average of non-insurance and insurance-related activities calculated in Step 1. The Regions and ONES execute NCUA's examination programs; thus, the budgeted costs related to these offices should receive the same allocation basis as the programs themselves. The allocation factor is based on principles 1, 2, and 3 as documented in Table 1. The budget for the regional offices and ONES is allocated at 61.0 percent for insurance-related activities.

Asset Management Assistance Center

NCUA conducts credit union liquidations and performs management and recovery of assets through the Asset Management and Assistance Center. The Asset Management Assistance Center assists NCUA regional offices with the review of large, complex loan portfolios and actual or potential bond claims. It also participates extensively in the operational phases of conservatorships and records reconstruction. The purpose of the Asset Management Assistance Center is to manage and reduce costs to the Share Insurance Fund and credit union members of credit union failures. Thus, OTR allocation is based on principle 4 at 100 percent insurance related.

Office of Consumer Financial Protection and Access

This division is responsible for NCUA's consumer financial literacy efforts, consumer inquiries and complaints, consumer protection compliance and rulemaking, fair lending examinations, interagency coordination and outreach, chartering and field-of-membership matters, low-income designations, charter conversions, and bylaw amendments. The majority of the work performed by the Office of Consumer Financial Protection and Access is related to NCUA's role as prudential regulator and

[59] The totals may not reconcile exactly due to rounding.

charterer of federal credit unions. This office is unique and differs from the Regions and ONES in the distribution and nature of work performed related to federal credit unions. Thus, principle 3 is applied to the majority of this office's work and allocated at 0 percent insurance related. However, some work the office performs involves federally insured state-chartered credit unions, which falls under principle 4. The office also addresses share insurance coverage matters, which also falls under principle 4.

The composite rate of this office's insurance-related activities calculates as 13 percent as reflected in Table 3. Thus, an allocation factor of 13 percent is applied to the office's financial budget in the OTR calculation.

TABLE 3—ALLOCATION OF THE OFFICE OF CONSUMER PROTECTION AND FINANCIAL ACCESS STAFF TIME

Division	Number of staff (full time equivalent)	Staff time spent on activities (full time equivalent)	Allocation factor (percent)	Proportion of staff insurance-related work (full time equivalent)
Administrative	3			
—Principle 3 Activities		2.7	0	0.0
—Principle 4 Activities		0.3	100	0.3
Consumer Access	20			
–Principle 3 Activities		15.0	0	0.0
—Principle 4 Activities		5.0	100	5.0
Consumer Affairs	12			
—Principle 3 Activities		11.4	0	0.0
—Principle 4 Activities		0.6	100	0.6
Consumer Compliance Policy and Outreach	10			
—Principle 3 Activities		10.0	0	0.0
—Principle 4 Activities		0.0	100	
Totals	45			5.9
Insurance-Related Full Time Equivalent Staff to Total Staff	13%			

The office's administrative staff provides support for the whole office. Ten percent of this unit's work was devoted to supporting insurance-related functions, like responding to consumer inquiries on share insurance coverage. Thus, principle 4 is applied to those activities as 100 percent insurance related while the remaining 90 percent of their time was spent supporting charting, bylaw, field of membership, and related activities, which fall under principle 3 as 0 percent insurance related.

The Division of Consumer Access staff spent 25 percent of their time addressing insurance-related functions, like insurability standards for mergers and insurance applicants where principle 4 applies. The remainder of this unit's time was spent processing various chartering and field of membership expansion applications and bylaw matters where principle 3 applies.

The Division of Consumer Affairs staff spent 5 percent of its time addressing share insurance questions received from consumers which falls under principle 4. The division spent the remaining 95 percent of its time on consumer related activities like administering the Financial Literacy Program, which falls under principle 3.

The Division of Consumer Compliance Policy and Outreach focuses on issues related to consumer regulations including implementing the Equal Credit Opportunity Act, the Home Mortgage Disclosure Act, the Truth in Lending Act, and the Real Estate Settlement Procedures Act. All of these activities fall under principle 3; therefore, 100 percent of the division's staff time is allocated as 0 percent insurance related.

Office of Small Credit Union Initiatives

The proposed methodology allocates the cost of the Office of Small Credit Union Initiatives based on principles 1 and 2. The office tracks the time the Economic Development Specialists spent consulting and training both federal credit unions and federally insured state-charted credit unions. The proportion of time spent on federal credit unions is allocated based on principle 1 while federally insured state-chartered credit union work is allocated based on principle 2. Other office personnel process grants and loans for both federal credit unions and federally insured state-chartered credit unions. Grant and loan activities are allocated the same way as the consulting and training time using principles 1 and 2. The resulting allocation factor for the Office of Small Credit Union Initiatives is 60 percent as shown in Tables 4 and 5.[60]

Table 4 illustrates the allocation for the Office of Small Credit Union Initiative's consulting hours between federal and state-chartered credit unions applied to the budgeted hours for 2017. Principle 1 is applied for federal charters and principle 2 is applied for state charters. The result is a composite rate of 59.3 percent insurance-related hours for the Economic Development Specialists.

[60] About 73% of all grants and loans processed by the Office of Small Credit Union Initiatives in 2016 were for federal credit unions. Of the 18,633 hours budgeted for Economic Development Specialist consulting and training, about 81% is for federal credit unions.

TABLE 4—2017 ECONOMIC DEVELOPMENT SPECIALIST WORKLOAD ALLOCATION

Charter type	Budget (hours)	Percent insurance related	Hours insurance related	Percent of budget insurance related
Federal Charter	15,185	50	7,592	40.7
State Charter	3,448	100	3,448	18.5
Total	18,633	N/A	11,040	59.3

Table 5 illustrates the allocation of the grant and loan activities performed by the Office of Small Credit Union Initiatives by charter type. Principle 1 is applied for federal charters and principle 2 is applied for state charters. This results in a composite rate of 63.7 percent insurance-related activities for grants and loans.

TABLE 5—GRANT APPROVAL AND LOAN DISBURSEMENT 2016 BY CHARTER TYPE [61]

Charter type	Total grants and loans	Percent insurance-related	Total insurance-related	Percent of total
Federal Charter	235	50	118	36.3
State Charter	89	100	89	27.5
Total	324	N/A	207	63.7

Table 6 shows the resulting overall composite rate of 59.8 percent insurance-related activities for the Office of Small Credit Union Initiatives. This factor is applied to the financial budget for this office in the OTR calculation.

TABLE 6—ALLOCATION OF THE FINANCIAL BUDGET

Staff	Budget	Insurance-related (percent)	Budget allocation
Economic Development Specialists	3,733,000	59.3	2,211,982
Grants and Loans	527,000	63.7	335,881
Total	4,260,000	59.8	2,547,773

All Other Offices

NCUA's remaining offices design or oversee the agency's mission and its related offices, or provide necessary support to mission offices or the entire agency. As such, the proportion of insurance-related activities for these offices corresponds to that of the mission offices. It would be administratively burdensome to attempt to account for any variation in activity levels from the mission functions, and would not result in a material difference in outcomes. Therefore, these office costs are allocated based on the weighted average of insurance-related activities calculated in the subtotal of agency costs for the offices above that have a distinct allocation factor. The budgeted costs for the following offices are allocated at 60.0 percent insurance-related activities for purposes of calculating the OTR:

- NCUA Board,
- Executive Director,
- General Counsel,
- Chief Financial Officer,
- Chief Information Officer,
- Chief Economist,
- Human Resources,
- Examination and Insurance,
- Inspector General,
- Minority and Women Inclusion,
- Public and Congressional Affairs, and
- Continuity and Security Management.

c. Step 3—Calculate the OTR

The OTR represents the percentage of the NCUA Operating Budget that is funded by a transfer from the Share Insurance Fund.[62] Using the result from Step 2, the OTR calculation is shown in Table 7.

TABLE 7—OTR CALCULATION

Operating Costs to be Borne by the Share Insurance Fund	$179.0
÷ Total Operating Budget	$298.2
= OTR	60.0%

Based on data used to determine the OTR for 2017, the proposed changes to the OTR methodology would result in an OTR of 60.0 percent. The current methodology resulted in an OTR of 67.7 percent for 2017. Table 8 summarizes the results for the 2017 OTR calculation using the current and proposed methodologies.

[61] Numbers may not reconcile exactly due to rounding.

[62] The percentage of actual expenses funded by the Share Insurance Fund as they are incurred each month.

TABLE 8—2017 OTR RESULTS COMPARISON

	Current methodology	Proposed methodology	Change [63]
OTR Percent	67.7%	60.0%	−7.70%
OTR $ Millions	$201.8	$179.0	−$22.8

For informational purposes only, Table 9 illustrates the portion of NCUA's total Operating Budget costs funded explicitly and implicitly by federal credit unions and federally insured state-chartered credit unions respectively.

TABLE 9—OPERATING BUDGET COST DISTRIBUTION

Portion of 2017 operating budget covered by:	Federal credit unions	Federally insured state-chartered credit unions
Federal Credit Union Operating Fee	40.0%	0.0%.
OTR (proportional based on insured shares)	30.8%	29.2%.
	(60.0% × 51.3%).	(60.0% × 48.7%).
Total	70.8% [64]	29.2%.

The proposed change to the OTR methodology would result in the annual Operating Fee paid by federal credit unions increasing by about 24%—an increase of $22.8 million from $96.4 million to $119.2 million. Based on the 2017 Operating Fee scale, Table 10 provides several examples of how a federal credit union's operating fee would increase.

TABLE 10—EXAMPLES OF OPERATING FEE INCREASE FOR FEDERAL CREDIT UNIONS

Asset size of federal credit union	Increase to annual operating fee
$9.46 billion	$133,234
$1.01 billion	51,143
$503 million	25,445
$100 million	5,060
$50 million	2,526
$10 million	505
$1 million	0

V. Request for Comment

In addition to the proposed changes to the OTR methodology, the Board proposes to formally adopt the following OTR related processes:

- To solicit through the **Federal Register** public comment on the OTR methodology at least every 3 years, and whenever NCUA seeks to change the OTR methodology.
- Maintain the staff delegation to administer the OTR methodology but require public board briefings every year, no later than each December, on the results of the calculation and to post all related materials to NCUA's Web site.
- As part of future rulemaking, indicate for any proposed regulation involving the activities and authorities of credit unions whether the regulation is based on Title I, Title II, and/or Title III of the Act and seek comment on this determination. While the proposed new OTR methodology would no longer rely on mapping of regulations, this will increase clarity regarding the purpose of and authority for any new or updated regulations and preserve future flexibility with respect to any desired changes to the OTR methodology.

The Board seeks comments on all the proposed revisions to the OTR methodology and formal adoption of the procedures discussed above. In particular, the Board is interested in comments on alternative approaches to arriving at an allocation factor for the cost of examining and supervising federal credit unions (principle 1). For example, within the context of the overall simplification of the OTR methodology, should federal credit union examination and supervision activity be allocated primarily to the operating fee, or should it continue to reflect that much of NCUA's examination and supervision focus is on managing risk to the Share Insurance Fund.[65]

Commenters are also encouraged to discuss any other relevant issues they believe NCUA should consider with respect to the OTR methodology and, to the extent feasible, provide documentation to support any recommendations.

By the National Credit Union Administration Board on June 23, 2017.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2017–13635 Filed 6–29–17; 8:45 am]

BILLING CODE 7535–01–P

OFFICE OF PERSONNEL MANAGEMENT

Notice of Submission for Approval: Questionnaire for Non-Sensitive Positions (SF 85)

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The National Background Investigation Bureau (NBIB), U.S. Office of Personnel Management (OPM) is notifying the general public and other Federal agencies that OPM is seeking Office of Management and Budget (OMB) approval of a revised information collection, Questionnaire for Non-Sensitive Positions, (SF 85).

DATES: Comments are encouraged and will be accepted until August 29, 2017.

[63] For 2017, the proposed OTR methodology calculation would result in a decline of 11.4% from the current methodology.

[64] Based on the current OTR methodology, 67 percent of the total 2017 Operating Budget is covered by federal credit unions through Operating Fees and the OTR: *https://www.ncua.gov/About/Documents/Agenda%20Items/AG20416117Item4a.pdf.*

[65] To provide context for commenters, an assumption under principle 1 in the proposed OTR methodology that only the examination and supervision of troubled federal credit unions was insurance-related would result in an OTR of about 31 percent. Conversely, if the results of the Examiner Time Survey (about 88 percent insurance-related) were used for the allocation factor for principle 1 in the proposed OTR methodology, it would result in an OTR of about 85 percent.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to NBIB, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Donna McLeod or by electronic mail at *FISFormsComments@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the NBIB, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Donna McLeod or by electronic mail at *FISFormsComments@opm.gov.*

SUPPLEMENTARY INFORMATION: OPM is soliciting comments for this collection as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Questionnaire for Non-Sensitive Positions, SF 85, including accompanying releases, housed in a system named e-QIP (Electronic Questionnaires for Investigative Processing), is an information collection completed by applicants for, or incumbents of, Federal Government civilian positions, and other individuals performing work on behalf of the Federal Government and requiring logical and physical access to Federal systems and facilities, *e.g.,* pursuant to a Government contract. The collection is used by:

- The Federal Government in conducting background investigations of persons under consideration for non-sensitive, low-risk positions as defined in Executive Order 13764 and 5 CFR part 731;
- agencies in determining whether a person performing work for or on behalf of the Federal Government should be deemed eligible for physical and logical access to federally controlled facilities or information systems.

The SF 85 is completed by applicants for, or incumbents of, Federal Government civilian positions, or other individuals requiring logical or physical access to perform work on behalf of the Federal Government. For applicants, the SF 85 is to be used only after a conditional offer of employment has been made, unless OPM has provided an exception. The Electronic Questionnaires for Investigations Processing (e-QIP) is a web-based system application that houses the SF 85. A variable in assessing burden hours is the nature of the electronic application. The electronic application includes branching questions and instructions which provide for a tailored collection from the respondent based on varying factors in the respondent's personal history. The burden on the respondent is reduced when the respondent's personal history is not relevant to particular question, since the question branches, or expands for additional details, only for those persons who have pertinent information to provide regarding that line of questioning. Accordingly, the burden on the respondent will vary depending on whether the information collection relates to the respondent's personal history.

OPM proposes new changes to the SF 85. The instructional portion of the form will be modified. OPM will provide additional information regarding the investigative process. OPM will remove instructions that were needed only for persons completing a paper form, as the form is now collected by OPM only through electronic means. The Privacy Act Routine Uses provided on the form were updated to conform to the most recent publication of the OPM/Central 9 Personnel Investigations Records system of records notice. Section 6, your ''Identifying Information'' will be expanded to request additional identifiers. OPM will request, in Section 7, ''Your Contact Information'' that the respondent provide three contact numbers to facilitate contact between investigative personnel and the respondent; however respondents will be advised that only one number is required. Section 9, ''Citizenship'' will be expanded to collect additional information to assist in verifying derived citizenship of respondents born outside of the U.S. Section 10, ''Dual/Multiple Citizenship'' will include questions regarding the time period(s) of dual/multiple citizenship and an explanation of how such citizenship was acquired. Section 11, ''Where You Have Lived'' will include branching questions that replace detailed instructions for all respondents and instead tailor the collection to elicit information based on the respondent's relevant personal history. Section 12, ''Where You Went to School'' instructions will be changed regarding the requirement to list degree or diploma information. Section 13a, ''Employment Activities-Employment & Unemployment Record'' branching questions will be added to reduce detailed instructions for all respondents and tailor instructions as applicable to the respondent. Additionally, branching questions for foreign addresses and contacts will be added to assist with conducting the background investigation. Section 13b, ''Employment Activities-Former Federal Service'' will be added to capture former federal civilian service, excluding military service not previously provided. Section 13c, ''Employment Record'' branching questions will be added to prompt the applicant to enter the required information following each positive response.

In an effort to streamline information collection from the respondents, changes are proposed to add five areas of questioning found on the Declaration of Federal Employment form (OF 306) to the SF 85. The recommendation is to have questions pertaining to Selective Service record, military discharge, police records and court(s) martial, debarment from federal employment, and financial history included on the SF 85. This change would provide information needed in support of the background investigation and limit multiple reporting requirements for respondents for the purpose of the background investigation.

Section 15, ''Military History'' branching questions will be added to collect information pertaining to the types of military discharge received and information regarding military disciplinary actions. Branching questions will be added to elicit information regarding foreign military service, if applicable, in addition to U.S. military service, and to collect details of such service. Section 17, ''Police Record'' will include questions regarding offenses, charges, and arrests, and branching questions will be added to inquire about the disposition of criminal proceedings. Section 21, ''Financial Record'' will be added with branching questions to elicit specific detailed information pertaining to

failure to file or pay Federal, state, or other taxes when required by law or ordinance and to collect information regarding delinquent federal debt.

Section 16, ''People Who Know You Well'' branching questions will be added to clarify and collect additional information pertaining to the references. Section 18, ''Illegal Use of Drugs and Drug Activity'' will include instruction to clarify that drug use or activity illegal under Federal laws must be reported, even if that use or activity is legal under state or local law(s). Branching questions will be added regarding drug treatment details, which is pertinent information needed to support final adjudication. Section 19, ''Investigations and Clearance Record'' will be added with branching questions to elicit information necessary to obtain relevant details regarding prior records, including debarment from government employment. Section 22, ''Association Record'' will be added with branching questions which collect detailed information pertinent to a respondent's involvement in terrorist organizations, association with persons involved in activities to further terrorism and/or to overthrow the U.S. Government by force or violence.

The general ''Authorization for Release of Information'' will include clarifying language noting that information gathered during the investigation may include publicly available electronic information, including electronic social media information that has been published or broadcast for public consumption, is available on request to the public, is accessible on-line to the public, is available to the public by subscription or purchase, or is otherwise lawfully accessible to the public. A change is also proposed to the expiration timeframe of the General Release to five years. This change is consistent with the investigative coverage period for low risk, non-sensitive positions. In the event that review of financial information is needed for a particular investigation, the ''Fair Credit Reporting Disclosure and Authorization'' will be added to the collection.

Analysis

Agency: NBIB, U.S. Office of Personnel Management.

Title: Questionnaire for Non-Sensitive Positions (SF 85).

OMB Number: 3206–0261.

Affected Public: The SF 85 is an information collections completed by applicants for, or incumbents of, Federal Government civilian positions, or positions in private entities performing work for the Federal Government under contract. The SF 85 will be used by the Federal Government in conducting background investigations and reinvestigations of persons under consideration for, or retention in, non-sensitive positions. The form may also be used by agencies in determining whether a subject performing work for, or on behalf of, the Government under a contract, should be deemed eligible for logical or physical access. For applicants, the SF 85 is to be used only after a conditional offer of employment has been made, unless an exception is provided by OPM.

Number of Respondents: 55,040.

Estimated Time per Respondent: 120 minutes.

Total Burden Hours: 110,080.

U.S. Office of Personnel Management.

Kathleen M. McGettigan,

Acting Director.

[FR Doc. 2017–13819 Filed 6–29–17; 8:45 am]

BILLING CODE 6325–53–P

OFFICE OF PERSONNEL MANAGEMENT

Hispanic Council on Federal Employment

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The Hispanic Council on Federal Employment (Council) meeting will be held on Tuesday, August 1, 2017 at the following time and location shown below:

Time: 2:00 p.m. to 3:30 p.m.

Location: Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Executive Conference Room.

The Council is an advisory committee composed of representatives from Hispanic organizations and senior government officials. Along with its other responsibilities, the Council shall advise the Director of the Office of Personnel Management on matters involving the recruitment, hiring, and advancement of Hispanics in the Federal workforce. The Council is co-chaired by the Director of the Office of Personnel Management and the Chair of the National Hispanic Leadership Agenda (NHLA).

The meeting is open to the public. Please contact the Office of Personnel Management at the address shown below if you wish to present material to the Council at any of the meetings. The manner and time prescribed for presentations may be limited, depending upon the number of parties that express interest in presenting information.

FOR FURTHER INFORMATION CONTACT: Zina Sutch, Director, for the Office of Diversity and Inclusion, Office of Personnel Management, 1900 E Street NW., Suite 5H35, Washington, DC 20415. Phone (202) 606–2433 FAX (202) 606–6012 or email at *Zina.Sutch@opm.gov*.

U.S. Office of Personnel Management.

Kathleen McGettigan,

Acting Director.

[FR Doc. 2017–13818 Filed 6–29–17; 8:45 am]

BILLING CODE 6820–B2–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package 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: *Effective date:* June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. 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 June 21, 2017, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 46 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2017–153, CP2017–216.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–13689 Filed 6–29–17; 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: *Effective date:* June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. 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 June 21, 2017, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 331 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2017–152, CP2017–215.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–13690 Filed 6–29–17; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81020; File No. SR–MIAX–2017–30]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend MIAX Options Rules 307, Position Limits, and 309, Exercise Limits, To Extend the SPY Pilot Program

June 26, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 20, 2017, Miami International Securities Exchange, LLC (''MIAX Options'' or ''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 change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rules 307, Position Limits, and 309, Exercise Limits, to extend the pilot program that eliminates the position and exercise limits for physically-settled options on the SPDR® S&P 500® ETF Trust (''SPY Pilot Program'').

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Exchange Rules 307, Position Limits, and 309, Exercise Limits, establish position and exercise limits for aggregate positions in option contracts traded on the Exchange. Interpretations and Policies .01 to Rule 307 lists specific position limits for options on specific underlying securities, and Interpretations and Policies .01 to Rule 309 lists specific exercise limits for options on specific underlying securities. Among the listed specific underlying securities is the SPDR® S&P 500® ETF Trust (''SPY''). Currently, each of these Rules provides that there is no position limit and no exercise limit on options overlying SPY. The position and exercise limits for options overlying SPY in each of these Rules are the subject of a pilot program, which is scheduled to expire on July 12, 2017.[3]

The Exchange proposes to amend Exchange Rule 307, Interpretations and Policies .01, and Exchange Rule 309, Interpretations and Policies .01, to extend the duration of the SPY Pilot Program through July 12, 2018. There are no substantive changes being proposed to the SPY Pilot Program. The Exchange affirms its consideration of several factors that support the proposal to establish and extend the SPY Pilot Program, which include: (1) The liquidity of the option and the underlying security; (2) the market capitalization of the underlying security and the securities that make up the S&P 500 Index; (3) options reporting requirements; and (4) financial requirements imposed by MIAX Options and the Commission.

The Exchange notes that it is not aware of any problems created by the current SPY Pilot Program and does not foresee any problems with the proposed extension. The Exchange has formally submitted a Report for the SPY Pilot Program as part of this filing.[4] In addition, the Exchange represents that if it chooses to extend or seek permanent approval of the SPY Pilot Program, the Exchange will submit another SPY Pilot Program Report at least thirty (30) days prior to the expiration of the extended SPY Pilot Program time period which would cover the period between reports. The SPY Pilot Program Report will compare the impact of the pilot program, if any, on the volumes of SPY options and the volatility in the price of the underlying SPY contract, particularly at expiration. The SPY Pilot Program Report will also detail the size and different types of strategies employed with respect to positions established in SPY options; note whether any problems, in the underlying SPY ETF or otherwise, arose as a result of the no-limit approach; and include any other information that may be useful in evaluating the effectiveness of the SPY Pilot Program. In preparing the Pilot Report, the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange would make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program.

The Exchange proposes to extend the SPY Pilot Program in order for the Exchange and the Commission to have additional time to evaluate the Pilot and its effect on the market and to determine whether to seek permanent approval. Prior to the expiration of the SPY Pilot Program and based upon the findings of the SPY Pilot Program Report, the Exchange will be able to either extend the SPY Pilot Program, adopt the SPY Pilot Program on a permanent basis, or terminate the SPY Pilot Program. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the extended SPY Pilot Program, the position limits for options overlying SPY would revert to limits in effect prior to the commencement of the SPY Pilot Program.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78120 (June 22, 2016), 81 FR 42032 (June 28, 2016) (SR–MIAX–2016–17) (extending the SPY Pilot Program to July 12, 2017).

[4] *See* Exhibit 3 attached hereto [sic].

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act [5] in general, and furthers the objectives of Section 6(b)(5) of the Act [6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that extending the SPY Pilot Program promotes just and equitable principles of trade by permitting market participants, including market makers, institutional investors and retail investors, to establish greater positions when pursuing their investment goals and needs. The Exchange believes that the elimination of position limits for SPY options would not increase market volatility or facilitate the ability to manipulate the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change is not designed to address any aspect of competition, whether between the Exchange and its competitors, or among market participants. Instead, the proposed rule change is designed to allow the SPY Pilot Program to continue as the Exchange believes other competing options exchanges will also extend the SPY Pilot Program for another year.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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 and Rule 19b–4(f)(6) thereunder.[7]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [8] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [9] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange stated that waiver of the operative delay would allow the SPY Pilot Program to continue uninterrupted at the Exchange. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2017–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2017–30. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2017–30, and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13705 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the 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.

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

[10] 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).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81022; File No. SR–OC–2017–02]

Self-Regulatory Organizations; OneChicago, LLC; Notice of Filing of Proposed Rule Change To Implement Four Decimal Pricing for Outright Transactions in Single Stock Futures

June 26, 2017.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 (the ''Act'')[1], notice is hereby given that on June 16, 2017, OneChicago, LLC (''OneChicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change 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. OneChicago has also filed this rule change with the Commodity Futures Trading Commission (''CFTC''). OneChicago filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act (''CEA'') on June 16, 2017.

I. Self-Regulatory Organization's Description of the Proposed Rule Change

OneChicago is proposing to amend OneChicago Rule 902 (Contract Specifications) to decrease the minimum price increment for outright Single Stock Futures (''SSFs'')[2] quotes and trades from $0.01 to $0.0001 per share, which results in a minimum price fluctuation of $0.01 per contract. OneChicago is proposing this change to permit market participants to more precisely price the interest rate component of SSFs. Unlike their underlying securities, which are typically priced directly by the value of the security itself, SSF prices are derived by adding an interest rate component to the price of the underlying security. As described in more detail below, interest rates are commonly quoted in basis points (''bps''), and the forward value of SSFs must accurately reflect these interest rates. As such, OneChicago believes that four decimal quoting and trading may assist market participants in pricing SSFs with the precision necessary to reflect the actual value of the interest rate component of the contract.

The minimum price fluctuation is set forth in OneChicago Rule 902, which provides general contract specifications for all OneChicago SSFs. Because the minimum price increment for blocks, EFPs, and spread transactions was already set at $0.0001, upon amending OneChicago Rule 902(e), all SSF trade types, including outright trades, will quote and trade with minimum fluctuations of $0.0001 (*i.e.,* one basis point per dollar).

Further, as currently drafted, OneChicago Rule 902(e) provides that the Exchange may amend the minimum price fluctuation for SSFs without amending the text of the rule itself. Specifically, the clause ''or as otherwise stated by the Exchange'' effectively permits the Exchange to set a minimum price fluctuation by notice or other means. OneChicago is now proposing to amend OneChicago Rule 902(e) to delete this clause, thereby providing certainty to market participants that the minimum price fluctuation is stated solely in OneChicago Rule 902, and will not be amended other than through the rule change process.

The text of the proposed rule change is attached as *Exhibit 4* to the filing submitted by the Exchange but is not attached to the published notice of the filing.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OneChicago 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 a summary 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

OneChicago is proposing to amend OneChicago Rule 902 (Contract Specifications) to decrease the minimum fluctuation for outright SSF quotes and trades from $0.01 to $0.0001 per share effective July 10, 2017.[3] Previously, the minimum price fluctuation for each contract was located in the OneChicago Rule 905 supplement. In 2011, OneChicago amended the pricing of block and EFP transactions in OneChicago Rule 905 to permit four decimal point trade prices.[4] In 2015, OneChicago similarly amended OneChicago Rule 905 to permit quoting and trading of spread transactions in four decimal places as well.[5] This expansion allowed these trades to be more precisely priced because, as described in detail below, the interest rate component of SSFs is expressed in basis points, and four decimal pricing would permit market participants to quote or trade at prices that translate to their desired basis point level.

This change will harmonize the pricing of all OneChicago trade types to four decimal places, and permit the same level of precision in central limit order book (''CLOB'') outright trades as is currently available for block trades. This change may also remove a potential barrier to entry to OneChicago's competitive marketplace, and could encourage market participants to transition away from the block marketplace and to the CLOB.

OneChicago acknowledges that sub-penny pricing is currently prohibited in NMS securities.[6] Although SSFs are not NMS securities, OneChicago believes it is warranted to discuss why four decimal pricing is appropriate in the SSF market, as well as why certain concerns highlighted by the rule's sub-penny prohibition would not apply to the SSFs listed by OneChicago.[7]

Interest Rate Component of SSFs

Unlike securities—which are assets—SSFs are contingent liabilities that represent the forward value of the underlying security. The primary

[1] 15 U.S.C. 78s(b)(7).

[2] An ''outright'' SSF trade is a non-block, non-EFP, non-spread trade.

[3] OneChicago's outright SSFs are currently quoted and traded in two decimal places, and are therefore settled on a per-contract basis with a minimum price fluctuation of $1.00 due to the 100 share per-contract multiplier. The Commission notes that the proposed rule change has become effective on June 16, 2017 and will be implemented on July 10, 2017.

[4] *See* Securities Exchange Act Release No. 65053 (August 8, 2011) (SR–OC–2011–01).

[5] *See* Securities Exchange Act Release No. 75464 (July 16, 2015) (SR–OC–2015–02).

[6] 17 CFR 242.612.

[7] OneChicago notes that equity options, like SSFs, also have a multiplier of 100 underlying shares, but are currently only quoted and traded in two decimal places. OneChicago believes it is appropriate to distinguish SSFs from equity options with regard to decimal quoting and trading. In OneChicago's view, unlike equity options, which are primarily used for hedging or speculating, the primary uses of SSFs are to (1) refinance equity positions by replacing them with positions in SSFs at more favorable interest rates, (2) loan or borrow securities, or (3) loan or borrow cash with securities as collateral. In each case, the ability for the SSF trade price to precisely target the desired interest rate of the transaction is a necessary component. Accordingly, providing for four decimal quoting and trading supports the key uses of SSFs.

difference in pricing between securities and the SSFs that overlay them is the interest rate component of the forward contract. The interest rate of an SSF represents the cost for an individual to hold the underlying equity—or in other words, the cost of carry. Interest rates are described in basis points, which are hundredths of one percentage point. For example, an interest rate of 1.25% can also be expressed as 125 basis points. Interest rates are relative, not static, values. Consequently, 125 basis points can represent a different dollar value depending on the notional amount the interest rate is applied to. Four decimal pricing is a necessary step towards allowing SSFs to be priced in the dollar value that translates to the desired basis point equivalent.

Since a trade in an SSF is not the purchase of an asset, but instead allows the individual to carry a position to a future time, the most accurate way to price the interest rate of the trade is in basis points. In order to trade in basis points, market participants need the ability to price trades to the fourth numerical decimal point.[8] The decimal pricing expressed in dollars and cents can simply be viewed as a translation tool to permit market participants to trade at their desired level of basis points.

OneChicago believes that two decimal pricing is not sufficient to translate a dollar value to an interest rate with precision. For example, an SSF bid-ask spread of $4.01 by $4.02 on a $4.00 underlying stock with sixty-four days left until expiration would represent a 1.40% (140 bps) difference between the best bid and best ask. Specifically, the bid at $4.01 translates to a 1.41% (141 bps) interest rate, whereas the offer at $4.02 translates to a 2.81% (281 bps) interest rate.[9] A market participant desiring to enter into a long position in the SSF at any interest rate between 140 bps and 281 bps would be prohibited from doing so by two decimal pricing, even if the seller was also willing to enter into a short position at that level.

Although SSF trade prices are represented in dollar values, they also encompass interest rate and time until expiration. By using the trade price and time until expiration, market participants can determine the corresponding interest rate of the trade. Likewise, if a market participant is seeking a particular interest rate, that market participant can calculate the trade price by taking into account the desired interest rate and days until expiry. This is distinguished from trading in the underlying securities where the trade price directly represents the value of the asset itself. Accordingly, when market participants trade an SSF, they are calculating the futures trade price by considering not only the stock price, but also the days left to expiry and the prevailing interest rate.[10]

Concerns Raised by Reg NMS

OneChicago has considered whether permitting market participants to quote and trade SSFs in up to four decimals will impose any burdens on or otherwise negatively impact the SSF marketplace.[11] OneChicago does not believe that permitting quoting and trading SSFs in up to four decimals will cause market participants to step ahead of each other's limit orders for nominal amounts, and thereby cause resting limit orders to lose their execution priority in the CLOB. Since $0.0001 in an SSF trade price may represent varying notional amounts depending on the trade price, quantity, and days left until expiry, OneChicago does not believe it is appropriate to prohibit four decimal pricing based on such a concern.[12] This is especially true in a low interest rate environment where market participants need to tailor their SSF trade prices with accuracy such that the resulting interest rate is in line with their expectations.

Additionally, unlike the equity markets in which hundreds of trades occur every second, OneChicago's markets are strictly governed to limit order frequency. The overwhelming majority of volume executed on the exchange occurs through the use of manual front-end systems, whereby the individual trader fills out each order ticket with the relevant order parameters. Further, even market participants trading programmatically (and who are not market-makers) are limited to a maximum of ten orders per second across all products, which minimizes the potential that any one market participant would repeatedly enter and modify orders in one particular product.

Accordingly, OneChicago believes that it is unlikely that limit orders will be frequently stepped ahead of due to the low messaging quantity threshold permitted by the Exchange. OneChicago notes on this topic that if a limit order loses execution priority to another limit order priced exactly $0.0001 above (in the case of a buy order) or $0.0001 below (in the case of a sell order) the resting order, this loss of priority typically would not have occurred for a nominal amount.[13] As described above, the fourth decimal place of an SSF trade can represent a different dollar value depending on the price of the underlying security and the days left until expiry of the futures contract. Accordingly, the Exchange believes that in most instances, the new limit order would have provided actual interest rate improvement over the resting order. In fact, the Exchange predicts that this rule change will encourage the entry of more competitive orders due to increased participation by both retail investors and market makers.[14]

Furthermore, OneChicago does not anticipate any capacity burden generated as a result of permitting four

[8] OneChicago notes that the greater number of numerical decimal places available in a trade price, the more precisely the basis point rate of a trade may be targeted. OneChicago believes that four decimal point pricing is currently sufficient to provide interest rate precision, while also avoiding increased complexity that may be associated with five or six (or greater) decimal point pricing. Due to the 100 share multiplier, per-share trade prices in four decimals would permit contract settlement in two decimal places.

[9] As an ancillary matter, OneChicago notes that the Exchange trading platform does not support market orders partly to protect market participants from inadvertently crossing these large interest rate spreads and executing at an unexpected or undesired interest rate. Limit orders are the only order type that allow participants to precisely target an interest rate with their order price.

[10] Interest rates are typically expressed in five decimal places (or alternatively, in basis points out to three decimal places). *See e.g.,* ICE Libor Historical Rates, *available at https://www.theice.com/marketdata/reports/170.*

[11] Rule 612 of Regulation NMS, 17 CFR 242.612, prohibits national securities exchanges from accepting or ranking orders in any NMS security priced greater than $1.00 per share in an increment smaller than $0.01. By prohibiting sub-penny pricing, Regulation NMS sought to prevent market participants from stepping ahead of each other for a nominal or infinitesimally small amount, thereby discouraging the use of limit orders, and also to prevent overburdening market participants' systems due to increased messaging traffic resulting from sub penny orders. Although SSFs are not NMS securities, OneChicago has considered the prohibition on sub-penny pricing in NMS securities, and has concluded that the concerns raised by sub-penny pricing are not applicable to SSFs and unnecessary to impose on the SSF market.

[12] The average trade quantity on the CLOB is 5 contracts. Accordingly, the fourth decimal place would represent, on average, a $0.05 difference in trade value, which may translate to a meaningful interest rate, depending on the trade price and time until expiration. On a typical CLOB trade, the fourth decimal place may represent 0.1 to 3 bps in interest. By way of example, a 5 contract trade at a futures trade price of $13.9835 results in a notional value of $6991.75. Without the third and fourth decimal places (a futures trade price of $13.98), the notional value would be $6990.00, a difference of $1.75.

[13] As described in footnote 12, $0.05 may represent a spectrum of interest rates, depending on the futures trade price and days remaining until expiry.

[14] OneChicago notes that its spread marketplace has been trading on a centralized order book in four decimal places since July 20, 2015. Since that time, OneChicago has not observed any instance in which a limit order for a spread transaction was stepped ahead of.

decimal quoting and trading, as OneChicago does not expect its messaging traffic to increase as a result of this change. Therefore, the Exchange does not believe quote submission or market data receipt will be impacted in any anyway. Moreover, four decimal pricing is currently commonplace in the futures industry outside of SSFs.[15]

Impact on Retail Investors

OneChicago believes that the primary beneficiaries of this rule change will be retail investors. OneChicago's SSFs offer retail investors an alternative to financing their equity securities positions via margin loan from their brokers, and offer these investors the ability to acquire synthetic exposure to equity securities at competitive financing rates. OneChicago believes the lack of four decimal pricing for outright trades has hampered the ability of the Exchange's market makers to make competitive markets which would allow retail investors to transact at competitive financing rates. With four decimal pricing in the CLOB for outright trades, OneChicago anticipates that new market makers will enter the marketplace and make more competitive markets, increasing trading activity on the CLOB.

Further, as stated above, this rule change will encourage market participants to transact in OneChicago's CLOB, rather than in the block marketplace, thereby increasing competition in trading and quoting these products. Currently, block trades, which are privately negotiated transactions available only to eligible contract participants, as that term is defined in section 1a(18) of the CEA,[16] are already priced in four decimals. This change will place retail investors, who may not access the block marketplace, on equal footing with these more sophisticated participants by permitting them to price their SSF trades in up to four decimals. As a result of this bifurcated structure in which sophisticated parties can transact blocks in four decimals, but retail investors may not, retail investors are at a disadvantage as they receive less competitive interest rates on their CLOB trades.[17] In addition to permitting retail investors to trade in four decimals, OneChicago anticipates this rule change will cause sophisticated participants who can already transact in four decimal places in the block marketplace to begin to transition their activity to the CLOB. By aggregating and concentrating more SSF activity in the CLOB, OneChicago expects that all market participants will transact at more competitive levels than those present today.

Monitoring of Four Decimal Trading

As stated above, OneChicago does not anticipate that the transition of outright SSF trading to four decimals will harm or disadvantage any market participant. Nonetheless, in order to address any concerns related to stepping ahead, the Exchange plans to monitor its trading activity to determine whether permitting outright SSFs to trade in up to four decimal places has caused any harm to investors or deterioration in market quality. OneChicago plans to monitor this in two ways. First, the Exchange plans to monitor its trading directly for any incidence of stepping ahead. To do so, the Exchange will implement surveillance procedures that identify instances in which a market participant uses the third or fourth decimal place to step ahead of limit orders on the CLOB. OneChicago will review such activity and determine whether there is a pattern or practice of conduct not in line with just and equitable principles of trade. Second, OneChicago will, on a periodic basis, assess its market quality by looking to various factors such as spreads, market depth, and number and diversity of market participants. Using this two-pronged approached, the Exchange can determine whether permitting quoting and trading of SSFs in up to four decimals has promoted market quality, while ensuring market integrity. If OneChicago makes the determination that four decimal pricing has harmed either market quality or integrity, the Exchange will amend OneChicago Rule 902 to return to two decimal pricing. In order to provide its market participants with sufficient notice regarding this this [sic] change, OneChicago plans to distribute a Notice to Members before implementing the change to permit its market participants to make any necessary technology or operational changes, which OneChicago anticipates will be minimal.

2. Statutory Basis

OneChicago believes that the proposed rule change is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Section 6(b)(5)[19] in particular. The proposed rule change furthers the objectives of Section 6(b)(5) because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because it would apply equally to all market participants. The ability to trade outright transactions in up to four decimal places will not be limited to any class of market participant, and all market participants are eligible to trade on OneChicago's CLOB. The requirements to trade on the CLOB are no more restrictive than the requirements to trade block, EFP, or spread transactions. Permitting outright transactions to trade in up to four decimal allows all OneChicago participants to trade in the same way, thereby promoting just and equitable principles of trade.

OneChicago has considered whether permitting SSFs to quote and trade in up to four decimal places could permit manipulation or other violative activity in either the underlying equity or SSF, and has determined that no such concern exists. Four decimal pricing for SSFs would not present any new methods for market participants to engage in behavior that may be violative of Exchange Rules or any applicable law.

Further, as currently drafted, OneChicago Rule 902(e) provides that the Exchange may amend the minimum price fluctuation for SSFs without amending the text of the rule itself. Specifically, the clause ''or as otherwise stated by the Exchange'' effectively permits the Exchange to set a minimum price fluctuation by notice or other means. OneChicago is now proposing to amend OneChicago Rule 902(e) to delete

[15] Many futures products tied to interest rates trade in greater than two decimals. Although the per-contract notional value in these products are usually larger than the typical outright SSF notional value, OneChicago believes the need for interest rate precision is consistent across all of these products.

[16] 7 U.S.C. 1a(18).

[17] Although block trades typically have greater trade quantities than outright trades, block trades may trade in minimum quantities as low as five contracts for OneChicago's NoDivRisk products. Currently, participants in the block marketplace receive more favorable interest rates than those in the outright CLOB marketplace due to (1) the ability to pre-hedge block trades, and (2) four decimal pricing, which is currently available in blocks but not for outright trades.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

this clause, thereby providing certainty to market participants that the minimum price fluctuation is stated solely in OneChicago Rule 902, and will not be amended other than through the rule change process. OneChicago believes that its existing surveillance systems and capacity is sufficient to monitor and review trading activity for any violative trading in the SSF market.

B. Self-Regulatory Organization's Statement on Burden on Competition

OneChicago does not believe that the rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, in that the rule change simply allows an additional type of transaction to be priced in up to four decimal places. This change will allow all market participants to more precisely price the interest rate component of their outright transactions. By pricing futures trades more precisely, market participants will be able to submit more competitive bids and offers on the Exchange. Further, as described above, OneChicago believes this rule change will increase competition in that it will allow all market participants to transact at four decimal places, and not just sophisticated parties who qualify as eligible contract participants.

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 proposed rule change has become effective on June 16, 2017 and will be implemented on July 10, 2017.

At any time within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[20]

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–OC–2017–02 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–OC–2017–02. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–OC–2017–02 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

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[20] 15 U.S.C. 78s(b)(1).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81018; File No. SR–FINRA–2017–023]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Reporting of Certain ATS Transactions in U.S. Treasury Securities

June 26, 2017.

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 June 23, 2017, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to amend FINRA Rule 6730 (Transaction Reporting) to provide a temporary exception to permit member alternative trading systems (''ATSs'') and member subscribers to report aggregate trade information to TRACE for certain transactions in U.S. Treasury Securities.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA has prepared summaries, set forth in sections A, B,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA is proposing to amend Rule 6730 to add new Supplementary Material .06 (Temporary Exception for Aggregate Transaction Reporting of U.S. Treasury Securities Executed in ATS Trading Sessions) to provide members additional time to report individual transactions in U.S. Treasury Securities, as required by Rule 6730 (Transaction Reporting), that occur on member ATSs as part of a trading session, as described below.

Background

FINRA Rule 6730 sets forth a member's trade reporting obligations with regard to transactions in TRACE-Eligible Securities, which, beginning July 10, 2017,[4] will include U.S. Treasury Securities.[5] Pursuant to Rule 6730, each FINRA member that is a ''Party to a Transaction'' [6] in a TRACE-Eligible Security is obligated to report the transaction to TRACE within the prescribed period of time. The term ''Party to a Transaction'' means an introducing broker-dealer, if any, an executing broker-dealer, or a customer.[7] Thus, in a transaction in a TRACE-Eligible Security executed through an ATS between members, each member (and the ATS itself) is considered a Party to a Transaction and is required to report the trade.[8] Specifically, the ATS is required to report two transactions to TRACE: (1) The purchase of the security from one counterparty and (2) the sale of the security to the other counterparty. In addition, each FINRA member counterparty is required to report a buy or a sell, as applicable, identifying the ATS as the counterparty to each trade.[9]

FINRA understands that ATSs that permit subscribers to trade U.S. Treasury Securities on their platforms may permit subscribers to initiate a ''trading session,'' which is a discrete or timed order-matching event during which one or more additional subscribers can interact with the original order on the opposite side of the market or add to the initial order on the same side of the market.[10] Although it is possible that some trading sessions involve a single transaction between two counterparties like a typical trade, FINRA understands that most trading sessions include multiple participants on one or both sides of the market during the time period the trading session is open.

For example, suppose Subscriber A initiates a trading session to sell $25 million of a particular U.S. Treasury Security at a specific price. In a typical crossing scenario involving an ATS, the ATS would match the incoming sell order with a buy order from Subscriber B thus executing some or all of the original order. In this scenario, under TRACE rules, Subscriber A is required to report a sell to the ATS for the amount crossed, and Subscriber B would report a purchase from the ATS for that same amount.[11] The ATS would report two trades: A purchase from Subscriber A and a sell to Subscriber B. Under current rules, all of the reports are required to reflect the same terms of the trade and the same Time of Execution.[12]

FINRA understands that trading sessions involving U.S. Treasury Securities can, and often do, work in very different ways. Using the above example, Subscriber A may initiate a trading session to sell $25 million in a particular U.S. Treasury Security at a specific price. Subscriber B, however, may only wish to purchase $10 million. In this case, although there will be a sell from Subscriber A to the ATS and a subsequent sell from the ATS to Subscriber B (and offsetting trades for the purchase from the ATS by Subscriber B and the purchase from Subscriber A by the ATS), there may be further activity during the trading session. To continue the example, after Subscriber B agrees to purchase $10 million, Subscriber C agrees to purchase $15 million at the same price (meaning that, at this point, Subscriber A has sold all $25 million of the initial order). Subscriber D then joins the trading session and offers to sell $10 million of the same U.S. Treasury Security at the same price. Subscriber E purchases $5 million, and Subscriber B decides to purchase an additional $5 million. If, after the period of time defined by the ATS, no further interest is indicated, the trading session closes.

Reporting Obligations Under Rule 6730

Using the above example, at the end of the trading session, the individual trades are as follows:

Trade No.	Time	Subscriber	Buy/Sell	Amount (in millions)
	11:34:02.000	Subscriber A	Sell	$25
1	11:34:03.155	Subscriber B	Buy	10
2	11:34:03.483	Subscriber C	Buy	15
	11:34:04.003	Subscriber D	Sell	10
3	11:34:05.002	Subscriber E	Buy	5

[4] *See* Securities Exchange Act Release No. 79116 (October 18, 2016), 81 FR 73167 (October 24, 2016) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of File No. SR–FINRA–2016–027). *See also Regulatory Notice* 16–39 (October 2016).

[5] Rule 6710(p) will define a ''U.S. Treasury Security'' as ''a security, other than a savings bond, issued by the U.S. Department of the Treasury to fund the operations of the federal government or to retire such outstanding securities.'' The term ''U.S. Treasury Security'' also includes separate principal and interest components of a U.S. Treasury Security that has been separated pursuant to the Separate Trading of Registered Interest and Principal of Securities (''STRIPS'') program operated by the U.S. Department of Treasury. *See* Rule 6710(p).

[6] *See* Rule 6710(e).

[7] *See supra* note 6.

[8] *See* Question 7.4 in FINRA's Reporting of Corporate and Agencies Debt Frequently Asked Questions: Who reports trades executed through electronic trading systems that are themselves broker-dealers? All FINRA members that are ''parties to a transaction'' have a trade reporting obligation under TRACE Rules. Where two FINRA members effect/execute a transaction through an electronic trading system that is registered as a broker-dealer, both members, as well as the electronic trading system would have a trade reporting obligation. *See* Reporting of Corporate and Agencies Debt Frequently Asked Questions, available at *http://www.finra.org/industry/faq-reporting-corporate-and-agencies-debt-frequently-asked-questions-faq#7-4. See also Regulatory Notice* 14–53 (November 2014).

[9] Whether the ATS is involved in the clearance and settlement of a transaction does not change the TRACE trade reporting obligation for trades occurring through its system. *Regulatory Notice* 14–53 (November 2014).

[10] Different members use varying nomenclature to describe trading sessions. For example, one member ATS refers to these sessions as ''workups'' or ''workup sessions.'' In addition, the length of time a session remains open and other characteristics of how a session is structured may change from member to member. As used in the proposed rule change, the term ''trading session'' is meant to capture all variations of such types of sessions that member ATSs may use.

[11] Examples assume that each subscriber is a FINRA member.

[12] Under Rule 6710(d), the ''Time of Execution'' for a transaction in any TRACE-Eligible Security means ''the time when the Parties to a Transaction agree to all of the terms of the transaction that are sufficient to calculate the dollar price of the trade.''

Trade No.	Time	Subscriber	Buy/Sell	Amount (in millions)
4	11:34:05.877	Subscriber B	Buy	5
	11:34:07.877	Trading Session Closes		

FINRA understand that, under current practices, after the close of the trading session an ATS will provide each subscriber with a single trade message indicating the subscriber's aggregate activity during the trading session (including, for example, an aggregate size and average price), and that the execution time provided to a subscriber can vary depending upon the convention used by the particular ATS. FINRA also understands that, although information on the individual transactions within the trading session is generally available on a real-time basis to the subscribers during the trading session to track the status of the order, this information is not included on the final trade message, which FINRA understands currently is the message that would be used systematically by the member ATS and its subscribers for transaction reporting purposes.

Under Rule 6730, each individual trade that occurs during a trading session is a separate transaction and, as such, must be reported individually. For example, using the example above, at 11:34:03.155 (''Trade No. 1''), there is a trade agreed to between Subscribers A and B and all of the terms of the trade that are sufficient to calculate the dollar price of the trade are known at that time, including the security, the price, and the parties to the trade (*i.e.,* the Time of Execution'').[13] Thus, under current rules and guidance, FINRA would expect the following trade reports for Trade No. 1:

- Subscriber A reports a sell to the ATS for $10 million in the security with a Time of Execution of 11:34:03.155.
- Subscriber B reports a purchase from the ATS for $10 million in the security with a Time of Execution of 11:34:03.155.
- The ATS submits two reports, a buy from Subscriber A and a sell to Subscriber B for $10 million in the security, both with a Time of Execution of 11:34:03.155.

The same analysis would apply for each of the other individual trades that occurred during the trading session. Thus, under current TRACE reporting rules, the following reports would be required by all Parties to a Transaction with respect to the trades during the trading session in the above example:

Trade No.	TRACE reports	Quantity (in millions)	Time of execution
1	Subscriber A sell to ATS	$10	11:34:03.155
	ATS buy from Subscriber A	10	11:34:03.155
	ATS sell to Subscriber B	10	11:34:03.155
	Subscriber B buy from ATS	10	11:34:03.155
2	Subscriber A sell to ATS	15	11:34:03.483
	ATS buy from Subscriber A	15	11:34:03.483
	ATS sell to Subscriber C	15	11:34:03.483
	Subscriber C buy from ATS	15	11:34:03.483
3	Subscriber D sell to ATS	5	11:34:05.002
	ATS buy from Subscriber D	5	11:34:05.002
	ATS sell to Subscriber E	5	11:34:05.002
	Subscriber E buy from ATS	5	11:34:05.002
4	Subscriber D sell to ATS	5	11:34:05.877
	ATS buy from Subscriber D	5	11:34:05.877
	ATS sell to Subscriber B	5	11:34:05.877
	Subscriber B buy from ATS	5	11:34:05.877

Proposed Temporary Relief

The proposed rule change will, until July 10, 2018, permit members the flexibility to report trades that occurred in a U.S. Treasury Security executed within discrete ATS trading sessions (sometimes referred to as ''work-up sessions'') on an aggregate, rather than individual, basis. The proposed rule change is intended to provide members with additional time to complete systems changes necessary to report each individual transaction in the trading session as required by Rule 6730, as discussed below.

FINRA understands that certain ATSs that are active in the market for U.S. Treasury Securities currently are set up to deliver aggregate trading session transaction information to each subscriber that participated in the trading session through a single trade message generated at the conclusion of a trading session. The ATSs use this final trade message for purposes of back office processes (which would include generating trade reports) and believe their subscribers use the final trade messages similarly. As a result, FINRA understands that significant systems changes would be required by the ATSs to create and generate the individual trade information within a trading session in a form that could be integrated into the ATSs', as well as their subscribers', back office processes to enable the reporting of individual, rather than aggregate, trading session transaction information to TRACE, and that these changes cannot be made by July 10, 2017. As a result, FINRA is proposing to provide a temporary exception by adopting Supplementary Material .06 to permit members to report to TRACE aggregate, rather than individual, transaction information reflecting the aggregate size and average price of such transactions, and to permit trade reports to use a Time of Execution communicated by the ATS to each Party to a Transaction.[14]

[13] *See supra* note 12.

[14] FINRA notes that, even where aggregation is not necessary because only the ATS and two subscribers ultimately participated in a trading session resulting in a single cross, the proposed rule change permits members the flexibility to report a Time of Execution that is communicated by the ATS to each party. Thus, even where the trading session involves only one cross, member TRACE reports may reflect a Time of Execution that is, for

FINRA believes it is appropriate to provide the proposed relief in recognition of the fact that impacted members are unable to implement necessary changes by the July 10, 2017 effective date for TRACE reporting of transactions in U.S. Treasury Securities. FINRA believes the proposal strikes an appropriate balance in that FINRA will continue to receive transaction information for purchases and sales that occur as part of an ATS trading session, albeit aggregated. A member ATS availing itself of this exception must provide individual transaction information for each trade in a U.S. Treasury Security occurring in a trading session to FINRA upon request. In addition, FINRA notes that transparency will not be impacted by the proposed temporary relief because transaction information in U.S. Treasury Securities currently is not subject to dissemination.

FINRA has filed the proposed rule change for immediate effectiveness. The operative date of the proposed rule change will be July 10, 2017 and it will sunset on July 10, 2018, which FINRA believes will provide members with the additional time necessary to complete necessary systems changes and result in a more orderly implementation of the TRACE reporting requirements for Treasury securities.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[15] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. Based on discussions with multiple member ATSs, FINRA believes that additional time is necessary to permit members to program systems to comply with Rule 6730, which, beginning on July 10, 2017, will require that members report to TRACE each individual transaction in a U.S. Treasury Security.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposed rule change should benefit members whose trades are executed on member ATSs as part of a trading session, as it provides members with additional time to build or upgrade systems to enable reporting of individual transactions in the trading section. While the proposed rule change will temporarily lessen the requirements on ATSs and their subscribers as compared to other market participants, FINRA believes the proposed rule change is appropriate to allow sufficient time to make the technological changes necessary to comply with the rule and such accommodation will be limited in duration. Moreover, FINRA retains the right to require a member ATS availing itself of this exception to provide individual transaction information for each trade in a U.S. Treasury Security occurring in a trading session upon request.

The proposed temporary relief is not expected to undermine the potential benefits of Rule 6730, as the transaction information reflecting the aggregate size and average price of such transactions should still assist the regulators to conduct monitoring and surveillance of the U.S. Treasury Securities markets, in order to detect potential disruptive trading practices and risks to market stability.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and subparagraph (f)(6) of Rule 19b–4 thereunder.[17]

FINRA has asked the Commission to waive the 30-day operative delay so that the proposal will become operative immediately upon filing. FINRA represents that it only recently was made aware of the significant technological changes to member systems that will be necessary to comply with FINRA's requirements to report transactions in U.S. Treasury Securities to TRACE. FINRA also represented that it was informed by members that these systems changes cannot be completed by July 10, 2017, the date on which the new reporting requirements come into force. The proposed rule change appears to be a reasonable accommodation for members who are affected by unforeseen difficulties associated with systems reprogramming because it is of reasonably short duration and FINRA will still be able to request full transaction information from an ATS that benefits from the accommodation. Therefore, to facilitate orderly application of the TRACE reporting rules on July 10, 2017, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest and designates the proposal operative upon filing.[18]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–FINRA–2017–023 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

example, the beginning of the trading session or the end of the trading session.

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 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 Commission has waived the five-day prefiling requirement in this case.

[18] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2017–023. 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 Web site (*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 Web site 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 FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2017–023 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13703 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81017; File No. SR–CBOE–2017–050]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend a Pilot Program That Eliminates Position and Exercise Limits for Physically-Settled SPDR S&P 500 ETF Trust ("SPY") Options

June 26, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 22, 2017, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") 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 Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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 the Substance of the Proposed Rule Change

The Exchange proposes to extend the operation of a pilot program that eliminates position and exercise limits for physically-settled SPY options ("SPY Pilot Program"). The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 4.11. Position Limits

No changes.

. . . *Interpretations and Policies:*

.01–.06 No change.

.07 The position limits under Rule 4.11 applicable to options on shares or other securities that represent interests in registered investment companies (or series thereof) organized as open-end management investment companies, unit investment trusts or similar entities that satisfy the criteria set forth in Interpretation and Policy .06 under Rule 5.3 shall be the same as the position limits applicable to equity options under Rule 4.11 and Interpretations and Policies thereunder; except that the position limits under Rule 4.11 applicable to option contracts on the securities listed in the below chart are as follows:

Security underlying option	Position limit
The DIAMONDS Trust (DIA)	300,000 contracts.
The Standard and Poor's Depositary Receipt Trust (SPY)	None.
The iShares Russell 2000 Index Fund (IWM)	500,000 contracts.
The PowerShares QQQ Trust (QQQ)	900,000 contracts.
The iShares MSCI Emerging Markets Index Fund (EEM)	500,000 contracts.

Position limits for SPY options are subject to a pilot program through [July 12, 2017] *July 12, 2018.*

.08 No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Interpretation and Policy .07 to Rule 4.11 (Position Limits) to extend the

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

duration of the SPY Pilot Program.[5] The SPY Pilot Program is currently scheduled to expire on July 12, 2017, and this proposal would extend the SPY Pilot Program through July 12, 2018. There are no substantive changes being proposed to the SPY Pilot Program.

In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported its original proposal to establish the SPY Pilot Program, which include: (1) The liquidity of the option and the underlying security; (2) the market capitalization of the underlying security and the securities that make up the S&P 500 Index; (3) options reporting requirements; and (4) financial requirements imposed by CBOE and the Commission. When the SPY Pilot Program was most recently renewed in July 2016, CBOE submitted a report providing an analysis of the SPY Pilot Program during the period June 2015 through April 2016 (the ''Pilot Report''). In the July 2016 extension, the Exchange stated that if it were to submit a proposal to either extend the SPY Pilot Program, adopt the SPY Pilot Program on a permanent basis, or terminate the SPY Pilot Program, it would submit another Pilot Report covering the period since the previous extension.[6] Accordingly, the Exchange is submitting another Pilot Report that details CBOE's experience with the SPY Pilot Program. The Pilot Report now includes the period of May 2016 through April 2017. The Pilot Report is attached as Exhibit 3 [sic]. CBOE notes that it is unaware of any problems created by the SPY Pilot Program and does not foresee any as a result of the proposed extension. In extending the SPY Pilot Program, the Exchange states that if CBOE were to propose another extension, permanent approval or termination of the SPY Pilot Program, the Exchange will submit another Pilot Report covering the period since the previous extension, which will be submitted at least 30 days before the end of the proposed extension. If the SPY Pilot Program is not extended or adopted on a permanent basis by July 12, 2018, position limits in SPY will revert to their Pre-Pilot levels.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that extending the SPY Pilot Program promotes just and equitable principles of trade by permitting market participants, including market makers, institutional investors and retail investors, to establish greater positions when pursuing their investment goals and needs. Extending the SPY Pilot Program will give the Exchange and the Commission additional time to evaluate the pilot and its effect on the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any aspect of competition, whether between the Exchange and its competitors, or among market participants. Instead, the proposed rule change is designed to allow the SPY Pilot Program to continue as the Exchange expects other SROs will propose similar extensions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[10] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to 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, noting that such waiver will allow the Exchange to extend the pilot program prior to its expiration on July 12, 2017. In addition, the Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow for the least amount of market disruption as the pilot will continue as it currently does maintaining the status quo. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[12]

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:

[5] *See* Securities Exchange Act Release Nos. 67937 (September 27, 2012), 77 FR 60489 (October 3, 2012) (SR–CBOE–2012–091); 70878 (November 14, 2013), 78 FR 69737 (November 20, 2013) (SR–CBOE–2013–106); 74149 (January 27, 2015) 80 FR 5606 (February 2, 2015) (SR–CBOE–2015–008); 75381 (July 7, 2015) 80 FR 40111 (July 13, 2015) (SR–CBOE–2015–065); and 78131 (June 22, 2016) 81 FR 42011 (June 28, 2016) (SR–CBOE–2016–052).

[6] *See* 81 FR at 42011.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the 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.

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] 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).

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–CBOE–2017–050 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2017–050. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2017–050, and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13702 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81019; File No. SR–MIAX–2017–29]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

June 26, 2017.

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 June 19, 2017, Miami International Securities Exchange LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the list of MIAX Select Symbols [3] contained in the Priority Customer Rebate Program (the ''Program'') [4] of the Exchange's Fee Schedule to delete the option class ''YHOO'' associated with Yahoo! Inc. (''Yahoo!''). The Exchange initially created the list of MIAX Select Symbols on March 1, 2014,[5] and has added and removed option classes from that list since that time.[6] On June 13, 2017, Yahoo completed the sale of its operating business to Verizon Communications Inc. Subsequently, Yahoo! was renamed Altaba Inc. (''Altaba''), and, effective June 19, 2017, began trading under the ticker symbol ''AABA.'' Because Altaba's assets consist primarily of equity investments, short-term debt investments, and cash, it was required to register as an investment company under the Investment Company Act of 1940. The completion of the sale of the operating business to Verizon did not otherwise affect shares of Yahoo! common stock, which now represent shares of common stock of Altaba after it registered as an investment company and changed its name to Altaba.[7]

The Exchange has decided not to include Altaba in the list of MIAX Select Symbols. Thus, the Exchange is amending its Fee Schedule to delete the symbol YHOO from the list of MIAX Select Symbols contained in the Program to correspond with this change. This amendment is intended to

[3] The term ''MIAX Select Symbols'' means options overlying AAL, AAPL, AIG, AMAT, AMD, AMZN, BA, BABA, BBRY, BIDU, BP, C, CAT, CBS, CELG, CLF, CVX, DAL, EBAY, EEM, FB, FCX, GE, GILD, GLD, GM, GOOGL, GPRO, HAL, HTZ, INTC, IWM, JCP, JNJ, JPM, KMI, KO, MO, MRK, NFLX, NOK, NQ, ORCL, PBR, PFE, PG, QCOM, QQQ, RIG, S, SPY, SUNE, T, TSLA, USO, VALE, VXX, WBA, WFC, WMB, WY, X, XHB, XLE, XLF, XLP, XOM, XOP and YHOO.

[4] *See* section (1)(a)(iii) of the Fee Schedule for a complete description of the Program.

[5] *See* Securities Exchange Act Release No. 71700 (March 12, 2014), 79 FR 15188 (March 18, 2014) (SR–MIAX–2014–13).

[6] *See* Securities Exchange Act Release Nos. 79301 (November 14, 2016), 81 FR 81854 (November 18, 2016) (SR–MIAX–2016–42); 74291(February 18, 2015), 80 FR 9841 (February 24, 2015) (SR–MIAX–2015–09); 74288 (February 18, 2015), 80 FR 9837 (February 24, 2015) (SR–MIAX–2015–08); 73328 (October 9, 2014), 79 FR 62230 (October 16, 2014) (SR–MIAX–2014–50); 72567 (July 8, 2014), 79 FR 40818 (July 14, 2014) (SR–MIAX–2014–34); 72356 (June 10, 2014), 79 FR 34384 (June 16, 2014) (SR–MIAX–2014–26); 71700 (March 12, 2014), 79 FR 15188 (March 18, 2014) (SR–MIAX–2014–13).

[7] *See* the home page of the Altaba Web site located at: *https://www.altaba.com/.*

eliminate any potential confusion and to make it clear to market participants that, effective June 19, 2017, Yahoo!/Altaba will not be a MIAX Select Symbol contained in the Program.

2. Statutory Basis

The Exchange believes that its proposal to amend its fee schedule is consistent with Section 6(b) of the Act [8] in general, and furthers the objectives of Section 6(b)(4) of the Act,[9] in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities, and 6(b)(5) of the Act,[10] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the proposal to delete the symbol YHOO from the list of MIAX Select Symbols contained in the Program is consistent with Section 6(b)(4) of the Act because the proposed change will allow for continued benefit to investors by providing them an updated list of MIAX Select Symbols contained in the Program on the Fee Schedule.

The Exchange believes that the proposal to amend an option class that qualifies for the credit for transactions in MIAX Select Symbols is fair, equitable and not unreasonably discriminatory. The Exchange believes that the Program itself is reasonably designed because it incentivizes providers of Priority Customer [11] order flow to send that Priority Customer order flow to the Exchange in order to receive a credit in a manner that enables the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants. The Program, which provides increased incentives in high volume select symbols, is also reasonably designed to increase the competitiveness of the Exchange with other options exchanges that also offer increased incentives to higher volume symbols.

The Exchange also believes that its proposal is consistent with Section 6(b)(5) of the Act because it will apply equally to all Priority Customer orders in MIAX Select Symbols in the Program. All similarly situated Priority Customer orders in MIAX Select Symbols are subject to the same rebate schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is a not a competitive filing but rather is designed to update the list of MIAX Select Symbols contained in the Program in order to avoid potential confusion on the part of market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[12] and Rule 19b–4(f)(2) [13] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MIAX–2017–29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2017–29. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2017–29 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13704 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f(b)(1) and (b)(5).

[11] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 100.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81024; File No. SR–ISE–2017–54]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Non-Priority Customer License Surcharge

June 26, 2017.

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 June 12, 2017, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to apply the Non-Priority Customer license surcharge set forth in Section IV.B of the Schedule of Fees to orders that are routed to away markets.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to apply the Non-Priority Customer (*i.e.,* Market Maker,[3] Non-Nasdaq ISE Market Maker,[4] Firm Proprietary [5]/Broker-Dealer,[6] and Professional Customer [7]) license surcharge set forth in Section IV.B of the Schedule of Fees to orders in those licensed products [8] that are routed to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan (the ''Plan''). The Exchange initially filed the proposed pricing changes on June 1, 2017 (SR–ISE–2017–50). On June 12, 2017, the Exchange withdrew that filing and submitted this filing.

Today, the Exchange charges Non-Priority Customers route-out fees for orders in Non-Select Symbols [9] that are routed to away markets in connection with the Plan. Specifically as set forth in Section IV.F of the Schedule of Fees, Non-Priority Customer orders pay a route-out fee of $0.95 per contract in Non-Select Symbols. The route-out fees offset costs incurred by the Exchange in connection with using unaffiliated broker-dealers to access other exchanges for linkage executions. In addition, as set forth in Section IV.B of the Schedule of Fees, the Exchange presently charges a $0.25 license surcharge for all Non-Priority Customer orders in NDX and a $0.10 license surcharge for all Non-Priority Customer orders in BKX (together, ''License Surcharge''). This License Surcharge currently applies to all BKX and NDX orders executed on the Exchange, but is not applied when those orders are routed to away markets in connection with the Plan. The Exchange therefore proposes to apply the License Surcharge to such orders, specifically by adding language in Section IV.B of the Schedule of Fees that the Non-Priority Customer License Surcharge applies to all executions in BKX and NDX, including executions of BKX and NDX orders that are routed to one or more exchanges in connection with the Plan. For example, all Non-Priority Customer orders in NDX that are routed to away markets would be assessed a $0.25 per contract License Surcharge and a $0.95 per contract route-out fee under this proposal.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [13] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[14] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [15]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* Rule 100(a)(25).

[4] A ''Non-Nasdaq ISE Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[5] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[6] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[7] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer. A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in ISE Rule 100(a)(37A).

[8] The Exchange assesses a license surcharge for NDX and BKX. BKX, which represents options on the KBW Bank Index (''BKX''), is currently not traded on the Exchange. NDX represents options on the Nasdaq-100 Index traded under the symbol NDX (''NDX'').

[9] ''Non-Select Symbols'' are options overlying all symbols that are not in the Penny Pilot Program. NDX and BKX are Non-Select Symbols.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[14] *See NetCoalition,* at 534–535.

[15] *Id.* at 537.

national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..'' [16] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange believes that its proposal to apply the License Surcharge to Non-Priority Customer orders in licensed products that are routed to away markets in connection with the Plan is reasonable and equitable because it offsets both the costs associated with executing orders on away markets as well as the licensing costs associated with listing and trading these products. In particular, the Exchange's route-out fees are presently not calculated to cover the licensing costs for BKX and NDX. The Exchange notes that a license agreement is required to trade these products regardless of whether the order is executed on the Exchange or routed to another exchange in connection with the Plan. As such, the Exchange believes that extending the License Surcharge to those orders that are routed to away markets (in addition to those orders executed on the Exchange) is a reasonable and equitable means of recovering the costs of the license. Furthermore, the Exchange must pay the actual transaction fees charged by the exchange the order is routed to, which includes the license surcharge that such exchange assesses for those products. The Exchange's route-out fees are currently not calculated to cover these license surcharges assessed by other exchanges and therefore seeks to recover these costs under this proposal. For example, an NDX order that is routed to the Chicago Board Options Exchange (''CBOE'') in connection with the Plan would be assessed a $0.25 license surcharge by CBOE on top of the actual transaction fees that CBOE would charge for the NDX order.[17] The Exchange's route-out fees are presently assessed as fixed fees, unlike other exchanges, which, in addition to a fixed route-out fee, assess the actual transaction fees charged by the exchange the order is routed to.[18]

The Exchange also believes that its proposal is reasonable and equitable because Non-Priority Customers would be able to avoid paying the License Surcharge by sending the Exchange orders in these licensed products to be routed to another market and only pay the Exchange's route-out fee. The Exchange would, however, still be required to pay all of the actual transaction fees (including the license surcharge) charged by the exchange the order is routed to. For example, a Non-Priority Customer order in NDX that is routed to CBOE today would only be assessed the $0.95 per contract route-out fee while the Exchange would pay the $0.25 per contract license surcharge on top of the actual transaction fees CBOE would charge for the NDX order. The Exchange therefore believes that it is reasonable and equitable to assess the License Surcharge to orders in those licensed products which are routed to other exchanges in order to avoid this scenario.

Finally, the Exchange believes that the proposed fee change is equitable and not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. In particular, the License Surcharge would be applied to all Non-Priority Customer orders in those licensed products which are routed to away markets in connection with the Plan. The Exchange believes it is equitable and not unfairly discriminatory to assess this surcharge on all participants other than Priority Customers because the Exchange seeks to encourage Priority Customer order flow and the liquidity such order flow brings to the marketplace, which in turn benefits all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed application of the License Surcharge to orders that are routed to one or more exchanges in connection with the Plan does not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition from other exchanges. If the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that its proposal will impair the ability of members to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[19] and Rule 19b–4(f)(2) [20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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:

[16] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[17] *See* CBOE's fee schedule, at: *https://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf.*

[18] *See, e.g.,* MIAX Options Fee Schedule, (1) Transaction Fees, (c) Fees and Rebates for Customer Orders Routed to Another Options Exchange, at: *https://www.miaxoptions.com/sites/default/files/page-files/MIAX_Options_Fee_Schedule_05012017.pdf.*

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 240.19b–4(f)(2).

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–ISE–2017–54 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–ISE–2017–54. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2017–54 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13709 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81021; File No. SR–NYSE–2017–17]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Require Listed Companies To Provide Advance Notice of Dividend Announcements to the Exchange

June 26, 2017.

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 June 13, 2017, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Listed Company Manual (the ''Manual'') to require listed companies to provide notice to the Exchange at least 10 minutes before making any public announcement with respect to a dividend or stock distribution in all cases, including outside of the hours in which the Exchange's immediate release policy is in operation. The proposed rule change is available on the Exchange's Web site 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 amend the Manual to require listed companies to provide notice to the Exchange at least 10 minutes before making any public announcement with respect to a dividend or stock distribution in all cases, including outside of the hours in which the Exchange's immediate release policy is in operation.

The Exchange's immediate release policy, set forth in Sections 202.05 and 202.06 of the Manual, already requires companies releasing material news between 7.00 a.m. ET and the NYSE close (generally 4.00 p.m. ET) to call the Exchange's Market Watch team at least 10 minutes before issuing their announcement to discuss the content of the announcement and also email a copy of the proposed announcement to Market Watch at least 10 minutes before its release. Listed companies announcing dividends during these hours are required to comply with the immediate release policy in connection with such announcement.

Section 204.12 of the Manual requires listed companies to give prompt notice to the Exchange as to any dividend action or action relating to a stock distribution in respect of a listed stock (including the omission or postponement of a dividend action at the customary time as well as the declaration of a dividend). This notice must be given at least ten days in advance of the record date and is in addition to the requirement to publicly disclose the information pursuant to the immediate release policy. The dividend notice must be given to the Exchange in accordance with Section 204.00.[4] Notice must be given as soon as possible after declaration and in any event, no later than simultaneously with the announcement to the news media.

In addition, Section 204.21 of the Manual requires listed companies to give prompt notice to the Exchange of the fixing of a date for the taking of a record of shareholders, or for the closing of transfer books (in respect of a listed security), for any purpose. The notice must state the purpose or purposes for which the record date has been fixed. This notice must be provided to the

[4] Section 204.00 requires that such notice must be provided via a web portal or email address specified by the Exchange on its Web site, except in emergency situations, when notification may instead be provided by telephone and confirmed by facsimile as specified by the Exchange on its Web site.

Exchange in accordance with Section 204.00.

The Exchange proposes to amend each of Sections 204.12 and 204.21 to specify that notice of any dividend or stock distribution required by Section 204.12 must be provided to the Exchange at least 10 minutes before any public announcement, including when such announcement is being made outside of Exchange trading hours. The principal effect of this amendment would be to require listed companies to provide 10 minutes advance notice to the Exchange with respect to a dividend announcement made at any time, rather than just during the hours of operation of the immediate release policy as is currently the case.

The Exchange also proposes to amend Section 202.06(B) to emphasize the Exchange's consistent interpretation of that rule as requiring listed companies to comply with the immediate release policy with respect to all announcements relating to a dividend or stock distribution.

The Exchange believes there are significant benefits to requiring listed companies to provide all announcements of dividends and stock distributions to the Exchange prior to their public dissemination. In particular, if the Exchange is provided dividend information prior to its public availability, Exchange staff will be able to address any issues that may arise in relation to any announcement of a dividend or stock distribution. The proposed advance notice requirement would enable Exchange staff to ensure that a listed company's proposed dividend schedule complied with applicable Exchange requirements, including the requirement to provide 10 days advanced notice of the record date, and that the company's disclosure of the application of the Exchange's ''ex'-dividend trading policy was accurate. The Exchange intends to have staff available at all times to review dividend notifications immediately upon receipt, regardless of what time or day of the week they are provided. The staff will contact a listed company immediately if there is a problem with its notification. Addressing problems with dividend notifications before they are issued publicly will avoid any confusion in the marketplace resulting from the dissemination of inaccurate information.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)[5] of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed amendment is consistent with the protection of investors and the public interest because it will ensure that Exchange staff is able to address any rule compliance problems with a listed company's dividend schedule before it is publicly announced.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change is consistent with Section 6(b)[7] of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed amendment is consistent with the protection of investors and the public interest because it will ensure that Exchange staff is able to address any rule compliance problems with a listed company's dividend schedule before it is publicly announced.

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.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2017–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2017–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2017–17 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13706 Filed 6–29–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81023; File No. SR–GEMX–2017–25]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Non-Priority Customer License Surcharge

June 26, 2017.

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 June 12, 2017, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to apply the Non-Priority Customer license surcharge set forth in Section I of the Schedule of Fees to orders that are routed to away markets.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to apply the Non-Priority Customer (*i.e.,* Market Maker,[3] Non-Nasdaq GEMX Market Maker,[4] Firm Proprietary [5]/Broker-Dealer,[6] and Professional Customer [7]) license surcharge set forth in Section I of the Schedule of Fees to NDX [8] orders that are routed to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan (the ''Plan''). The Exchange initially filed the proposed pricing changes on June 1, 2017 (SR–GEMX–2017–22). On June 12, 2017, the Exchange withdrew that filing and submitted this filing.

Today, the Exchange charges Non-Priority Customers route-out fees for orders in Non-Penny Symbols [9] that are routed to away markets in connection with the Plan. Specifically as set forth in Section II.A of the Schedule of Fees, Non-Priority Customer orders pay a route-out fee of $0.95 per contract in Non-Penny Symbols. The route-out fees offset costs incurred by the Exchange in connection with using unaffiliated broker-dealers to access other exchanges for linkage executions. Also as set forth in Section I of the Schedule of Fees, the Exchange presently charges a $0.25 license surcharge for all Non-Priority Customer orders in NDX (''NDX Surcharge''). The NDX Surcharge currently applies to all NDX orders executed on the Exchange, but is not applied when those orders are routed to away markets in connection with the Plan. The Exchange therefore proposes to apply the NDX Surcharge to such orders by adding language in note 9 of Section I of the Schedule of Fees to state that the NDX Surcharge applies to all NDX executions, including executions of NDX orders that are routed to one or more exchanges in connection with the Plan. As such, all Non-Priority Customer orders in NDX that are routed to away markets would be assessed a $0.25 per contract NDX Surcharge and a $0.95 per contract route-out fee.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [13] (''NetCoalition'') the D.C. Circuit upheld

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* Rule 100(a)(25).

[4] A ''Non-Nasdaq GEMX Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[5] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[6] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[7] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer. A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq GEMX Rule 100(a)(37A).

[8] NDX represents options on the Nasdaq-100 Index traded under the symbol NDX (''NDX'').

[9] ''Non-Penny Symbols'' are options overlying all symbols that are not in the Penny Pilot Program. NDX is a Non-Penny Symbol.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[14] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [15]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [16] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange believes that its proposal to apply the NDX Surcharge to Non-Priority Customer orders in NDX that are routed to away markets in connection with the Plan is reasonable and equitable because it offsets both the costs associated with executing orders on away markets as well as the licensing costs associated with listing and trading NDX. The Exchange's route-out fees are presently not calculated to cover the licensing costs for NDX. The Exchange notes that a license agreement is required to trade NDX regardless of whether the NDX order is executed on the Exchange or routed to another exchange in connection with the Plan. As such, the Exchange believes that extending the NDX Surcharge to NDX orders routed to away markets (in addition to those orders executed on the Exchange) is a reasonable and equitable means of recovering the costs of the license. Furthermore, the Exchange must pay the actual transaction fees charged by the exchange the NDX order is routed to, which includes the license surcharge that such exchange assesses for NDX orders. The Exchange's route-out fees are currently not calculated to cover these license surcharges assessed by other exchanges and therefore seeks to recover these costs under this proposal. For example, an NDX order that is routed to the Chicago Board Options Exchange (''CBOE'') in connection with the Plan would be assessed a $0.25 license surcharge by CBOE on top of the actual transaction fees CBOE would charge for the NDX order.[17] The Exchange's route-out fees are presently assessed as fixed fees, unlike other exchanges, which, in addition to a fixed route-out fee, assess the actual transaction fees charged by the exchange the order is routed to.[18]

The Exchange also believes that its proposal is reasonable and equitable because Non-Priority Customers would be able to avoid paying the NDX Surcharge by sending the Exchange NDX orders to be routed to another market and only pay the Exchange's route-out fee. The Exchange would, however, still be required to pay all of the actual transaction fees (including the license surcharge) charged by the exchange the order is routed to. For example, a Non-Priority Customer order in NDX that is routed to CBOE today would only be assessed the $0.95 per contract route-out fee while the Exchange would pay the $0.25 per contract license surcharge on top of the actual transaction fees CBOE would charge for the NDX order. The Exchange therefore believes that it is reasonable and equitable to assess the NDX Surcharge to NDX orders that are routed to other exchanges in order to avoid this scenario.

Finally, the Exchange believes that the proposed fee change is equitable and not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. In particular, the NDX Surcharge would be applied to all Non-Priority Customer orders routed to away markets in connection with the Plan. The Exchange believes it is equitable and not unfairly discriminatory to assess this surcharge on all participants other than Priority Customers because the Exchange seeks to encourage Priority Customer order flow and the liquidity such order flow brings to the marketplace, which in turn benefits all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed application of the NDX Surcharge to NDX orders that are routed to one or more exchanges in connection with the Plan does not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition from other exchanges. If the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that its proposal will impair the ability of members to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[19] and Rule 19b–4(f)(2) [20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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.

[14] *See NetCoalition,* at 534–535.

[15] *Id.* at 537.

[16] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[17] *See* CBOE's fee schedule, at: *https://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf.*

[18] *See, e.g.,* MIAX Options Fee Schedule, (1) Transaction Fees, (c) Fees and Rebates for Customer Orders Routed to Another Options Exchange, at: *https://www.miaxoptions.com/sites/default/files/page-files/MIAX_Options_Fee_Schedule_05012017.pdf.*

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 240.19b–4(f)(2).

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–GEMX–2017–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2017–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2017–25 and should be submitted on or before July 21, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2017–13708 Filed 6–29–17; 8:45 am]

BILLING CODE 8011–01–P

SELECTIVE SERVICE SYSTEM

Privacy Act; System of Records

AGENCY: Selective Service System.

ACTION: Notice of Amendment to Systems of Records.

SUMMARY: Selective Service System has amended an existing system of records subject to the Privacy Act of 1974. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of system of records maintained by the agency.

DATES: The changes became effective in 2012. The system has been operational for five years.

FOR FURTHER INFORMATION CONTACT: Chief Information Officer, Office of Information Technology, Operations Directorate, Selective Service System, 1515 Wilson Boulevard, Arlington, Virginia 22209–2425.

SUPPLEMENTARY INFORMATION: This notice serves to update, amend, and consolidate the System of Records Notice for SSS–5 Reserve Force and National Guard Personnel Records; SSS–6 Uncompensated Personnel Records; and SSS–8 Pay Records published in the **Federal Register** September 20, 2011, Vol. 76, No 182.

Authority: 5 U.S.C. 552a

SYSTEM NAME:

Integrated Mobilization Information Management System (IMIS) and Reserve and National Guard Personnel Records.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Headquarters, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The Selective Service System is an independent agency of the United States government that maintains information on those potentially subject to military conscription. The statutory mission of the Selective Service is to be prepared to provide trained and untrained personnel to the DoD in the event of a national emergency and to be prepared to implement an alternative service program for registrants classified as conscientious objectors. These records are maintained at the National Headquarters Office in Arlington, VA.

The Selective Service System's Integrated Mobilization Information Management System (IMIS) is an application created by the Agency to manage reserve force officers and resources assigned to the Agency, various budget allocations and expenditures, local area boards, state directors, and Agency material resources. The Agency developed IMIS to manage resources needed to facilitate mission readiness; resources consist of assigned personnel, material, and budget management.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records contain information relating to selection, placement and utilization of military personnel assigned to SSS such as name, rank, Social Security account number, date of birth, physical profile, residence and business addresses, and telephone numbers.

AUTHORITY OF MAINTENANCE OF THE SYSTEM:

Chapter 49, Military Selective Service Act (50 U.S.C. 3801 *et seq.*)

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

The purpose of these series of records is to provide information on Officers and Warrant Officers of the Reserves and National Guard currently assigned to the SSS. This system is used to verify payment information for reserve force officers assigned to the agency. Records includes full name of the individual, date of birth, selective service number (if available), mailing address, payment information, financial reports and reimbursements. Documents are scanned into this system for computer-based storage and shared with the National Business Center in Denver, Colorado. This system has some PII information unique solely to the system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data is kept secure in accordance with the National Institutes of Standards and Technologies' *Special Publication 800–53* guidelines and the *Federal Information Security Management Act of 2002.*

[21] 17 CFR 200.30–3(a)(12).

RETRIEVABILITY:

Records are indexed by name and Service Number.

SAFEGUARDS:

a. Use of the records or any information contained therein is limited to Selective Service System employees or Reserve Forces Members whose official duties require access.

b. Records maintained by authorized personnel only, who have been trained in the rules and regulations concerning disclosures of information.

c. Periodic security checks and other emergency planning.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Office of Information Technology, Operations Directorate, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425.

RETENTION AND DISPOSAL:

Temporary. Cutoff at the end of the calendar year. Destroy immediately after employee is no longer assigned to Selective Service System.

RECORD ACCESS PROCEDURES:

SSS Reserve Forces Members or former members who wish to gain access to their records should make their request in writing addressed to: Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425, Attn: Military Personnel.

It is necessary to include the Member's full name, rank, branch of service, address, and Social Security Account Number.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures, above.

RECORD SOURCE CATEGORIES:

Information in this system is obtained directly from the individual to whom it applies or is derived from information supplied or is provided by the individual Branch of the Armed Forces.

SYSTEMS EXEMPTED FOR CERTAIN PROVISIONS OF THE ACT:

None.

Dated: June 22, 2017.

Donald M. Benton,

Director.

[FR Doc. 2017–13768 Filed 6–29–17; 8:45 am]

BILLING CODE 8015–01–P

SELECTIVE SERVICE SYSTEM

Privacy Act; System of Records: Amendments

AGENCY: Selective Service System.

ACTION: Notice of Amendment to Systems of Records.

SUMMARY: Selective Service System has amended an existing system of records subject to the Privacy Act of 1974. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of system of records maintained by the agency.

DATES: The changes became effective in 2012. The system has been operational for five years.

FOR FURTHER INFORMATION CONTACT: Chief Information Officer, Office of Information Technology, Operations Directorate, Selective Service System, 1515 Wilson Boulevard, Arlington, Virginia 22209–2425.

SUPPLEMENTARY INFORMATION: This notice serves to update, amend, and consolidate the Systems of Records Notice for SSS–2 General Files Registrant Processing; SSS–3 Reconciliation Service Records; SSS–4 Registrant Information Bank Records; SSS–7 Suspected Violator Inventory System; and SSS–9 Registrant Reservation Records published in the **Federal Register** September 20, 2011, Vol. 76, No 182.

AUTHORITY:

5 U.S.C. 552a.

SYSTEM NAME:

Registration, Compliance and Verification (RCV) System

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Data Management Center, Operations Directorate, Great Lakes, Illinois 60088.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Registrants of the Selective Service System after 1979 (men born after December 31, 1959). Young men register upon reaching their 18th birthday. By current law, women are not required to register.

a. Registration Form.

b. Computer database, computer tape and microfilm copies containing information provided by the registrant on Registration Form.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Chapter 49, Military Selective Service Act (50 U.S.C. 3801 *et seq.*)

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

The *Military Selective Service Act,* Selective Service regulations, and the President's Proclamation on Registration requires those registering with Selective Service to provide their full name, date of birth, address, sex, Social Security Account Number, if they have one, and their signature. The principal purpose of the requested information is to establish or verify a person's registration with the Selective Service System. Registration information may be shared with the following government agencies for the purposes stated:

Department of Justice—For review and processing of suspected violations of the Military Selective Service Act (MSSA), for perjury, and for defense of a civil action arising from administrative processing under such Act.

Department of State and U.S. Citizenship and Immigration Services—For collection and evaluation of data to determine a person's eligibility for United States citizenship.

Department of Defense and U.S. Coast Guard—To exchange data concerning registration, classification, induction, and examination of registrants and for identification of prospects for recruiting.

Department of Labor—To assist veterans in need of data concerning reemployment rights, and for determination of eligibility for benefits under the Workforce Investment Act.

Department of Education—To determine eligibility for student financial assistance.

U.S. Census Bureau—For the purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13.

Office of Personnel Management and U.S. Postal Service—To determine eligibility for employment.

Department of Health and Human Services—To determine a person's proper Social Security Account Number and for locating parents pursuant to the Child Support Enforcement Act.

State and Local Governments—To provide data that may constitute evidence and facilitate the enforcement of state and local law.

Alternative Service Employers—During conscription, to exchange information with employers regarding a registrant who is a conscientious objector for the purpose of placement and supervision of performance of alternative service in lieu of induction into the military service.

General Public—Registrant's name, Selective Service Registration Number, Date of Birth and Classification, (Military Selective Service Act, 50 U.S.C. 3806(h)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on microfilm and in the computer system. Microfilm records are indexed by Document Locator Number, and the computer system lists these numbers for document retrieval from the microfilm records.

RETRIEVABILITY:

The system is indexed by Selective Service Number, but records can be located by searching for specific data.

SAFEGUARDS:

Measures that have been taken to prevent unauthorized disclosures of records are:

a. Records are maintained by authorized personnel only, who have been trained in the rules and regulations concerning disclosures of information; offices are locked when authorized personnel are not on duty, and are protected by an electronic security access system at all times.

b. Periodic security checks and other emergency planning.

c. Microfilm records transferred to a Federal Records Center for storage are boxed and taped; records in transit for temporary custody of another office are sealed.

d. Selective Service System employees access the application via customized user interface—access is controlled by user id and password credentials.

e. Records eligible for destruction are destroyed by maceration, shredding, burning or purging from the RCV database.

RETENTION AND DISPOSAL:

Individual Processing Records:

1. Registration Form—Destroyed by maceration when its information has been transferred onto microfilm, added to the computer system, and an image has been transferred to the National Archives. Original microfilm is stored at a Federal Records Center. A microfilm non-record copy is retained at the Data Management Center, in locked steel cabinets. The copies are retained until no longer needed for reference purposes. Also, registration files are stored on hard drives/network storage.

2. The record copy of microfilm and computer database will be retained until the registrant reaches 85 years of age.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Office of Information Technology, Operations Directorate, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425.

RECORD ACCESS PROCEDURES:

The agency office address to which inquiries should be addressed and the location at which an individual may present a request as to whether the RCV System (after 1979) contains records pertaining to himself is: Chief Information Officer, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425.

It is necessary to furnish the following information in order to identify the individual whose records are requested:

a. Full name of the individual.

b. Selective Service Number or Social Security Account Number, date of birth and address at the time of registration if Selective Service Number is not known.

c. Mailing address to which the reply should be mailed.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures, above.

RECORD SOURCE CATEGORIES:

Information contained in the Registrant Registration Records System is obtained from the individual.

SYSTEMS EXEMPTED FOR CERTAIN PROVISIONS OF THE ACT:

None.

Dated: June 22, 2017.

Donald M. Benton,

Director.

[FR Doc. 2017–13771 Filed 6–29–17; 8:45 am]

BILLING CODE 8015–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15187 and #15188; TENNESSEE Disaster #TN–00105]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of TENNESSEE

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of TENNESSEE (FEMA–4320–DR), dated 06/23/2017.

Incident: Severe Storms, Straight-line Winds, and Flooding.

Incident Period: 05/27/2017 through 05/28/2017.

DATES: Effective 06/23/2017.

Physical Loan Application Deadline Date: 08/22/2017.

Economic Injury (Eidl) Loan Application Deadline Date: 03/23/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/23/2017, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Blount, Cumberland, Fayette, Knox, Loudon, Morgan, Putnam, Rhea, Roane, Sevier, Shelby, Smith.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 15187B and for economic injury is 15188B.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–13748 Filed 6–29–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15138 and #15139; IDAHO Disaster Number ID–00067]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of IDAHO

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of IDAHO (FEMA–4313–DR), dated 05/18/2017.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 03/06/2017 through 03/28/2017.

DATES: Effective 06/22/2017.

Physical Loan Application Deadline Date: 07/17/2017.

Economic Injury (Eidl) Loan Application Deadline Date: 02/20/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of IDAHO, dated 05/18/2017, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Benewah

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–13749 Filed 6–29–17; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 10051]

E.O. 13224 Designation of Mohammad Yusuf Shah, aka Mohd Yusuf Shah, aka Mohammad Yousuf Shah, aka Mohd Yousuf Shah, aka Mohd Yosuf Shah, aka Mohammed Yusaf Shah, aka Syed Mohammed Yusuf Shah, aka Syed Salahuddin, aka Syed Salahudin, aka Sayeed Salahudeen, aka Peer Sahib, aka Salauddin as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the person known as Mohammad Yusuf Shah, also known as Mohd Yusuf Shah, also known as Mohammad Yousuf Shah, also known as Mohd Yousuf Shah, also known as Mohd Yosuf Shah, also known as Mohammed Yusaf Shah, also known as Syed Mohammed Yusuf Shah, also known as Syed Salahuddin, also known as Syed Salahudin, also known as Sayeed Salahudeen, also known as Peer Sahib, also known as Salauddin committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: June 26, 2017.

Rex Tillerson,

Secretary of State.

[FR Doc. 2017–13786 Filed 6–29–17; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice 10049]

30-Day Notice of Proposed Information Collection: Repatriation/Emergency Medical and Dietary Assistance Loan Application

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to July 31, 2017.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, 2201 C. St. NW., Washington, DC 20522, who may be reached at *RiversDA@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Repatriation/Emergency Medical and Dietary Assistance Loan Application.
- *OMB Control Number:* 1405–0150.
- *Type of Request:* Extension of a currently approved collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–3072.
- *Respondents:* U.S. Citizens applying for emergency loan assistance.
- *Estimated Number of Respondents:* 1,459.
- *Estimated Number of Responses:* 1,459.
- *Average Time per Response:* 20 minutes.
- *Total Estimated Burden Time:* 486 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The DS–3072 is an application for an

emergency loan for a destitute U.S. citizen and/or eligible family member to return to the United States or for a loan for a destitute U.S. citizen and/or eligible family member abroad to receive emergency medical and dietary assistance.

Methodology: The Bureau of Consular Affairs will post this form on Department of State Web sites to give respondents the opportunity to complete the form online, or print the form and fill it out manually and submit the form in person or by fax or mail.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizen Services, Department of State.

[FR Doc. 2017–13833 Filed 6–29–17; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Receipt of Noise Compatibility Program and Request for Review for Hawthorne Municipal Airport, Hawthorne, California

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces that it is reviewing a proposed noise compatibility program that was submitted for Hawthorne Municipal Airport under the Aviation Safety and Noise Abatement Act, (hereinafter referred to as ''the Act'') and 14 Code of Federal Regulations (CFR) part 150 by the City of Hawthorne, Los Angeles County, California. This program was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Hawthorne Municipal Airport were in compliance with applicable requirements, effective April 11, 2014, 79 FR 24488–24489. The proposed noise compatibility program will be approved or disapproved on or before December 20, 2017.

DATES: The effective date of the start of FAA's review of the noise compatibility program is June 23, 2017. The public comment period ends August 22, 2017.

FOR FURTHER INFORMATION CONTACT: Victor Globa, Federal Aviation Administration, Los Angeles Airports District Office, 15000 Aviation Boulevard, Room 3000, Lawndale, California 90261, Telephone: 310/725–3637. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA is reviewing a proposed noise compatibility program for Hawthorne Municipal Airport which will be approved or disapproved on or before December 20, 2017. This notice also announces the availability of this program for public review and comment.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of 14 CFR part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has formally received the noise compatibility program for Hawthorne Municipal Airport, effective on December 20, 2016. The airport operator has requested that the FAA review this material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 47504 of the Act. Preliminary review of the submitted material indicates that it conforms to 14 CFR part 150 requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before December 20, 2017.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety or create an undue burden on interstate or foreign commerce, and whether they are reasonably consistent with obtaining the goal of reducing existing non-compatible land uses and preventing the introduction of additional non-compatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments relating to these factors, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, Western-Pacific Region Office, Airports Division, Room 3012, 15000 Aviation Boulevard, Lawndale, California 90261

Federal Aviation Administration, Los Angeles Airports District Office, 15000 Aviation Boulevard, Room 3000, Lawndale, California 90261

City of Hawthorne, Mr. Arnold Shadbehr, Interim City Manager/ Director of Public Works/City Engineer, 4455 West 126th Street, Hawthorne, CA 90250–4482

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Hawthorne, California, on June 23, 2017.

Brian Q. Armstrong,

Acting Director, Office of Airports, AWP–600, Western-Pacific Region.

[FR Doc. 2017–13812 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2017–54]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of the FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before July 20, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0535 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West

Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *deana.stedman@faa.gov,* phone (425) 227–2148; or Alphonso Pendergrass, ARM–200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, email *alphonso.pendergrass@faa.gov,* phone (202) 267–4713.

This notice is published pursuant to 14 CFR 11.85.

Issued in Renton, Washington, on June 20, 2017.

Victor Wicklund,

Manager, Transport Standards Staff.

Petition for Exemption

Docket No.: FAA–2017–0535.

Petitioner: Embraer.

Section of 14 CFR Affected: § 25.901(c).

Description of Relief Sought: Embraer seeks relief from the *no single failure* requirement of § 25.901(c) of Title 14, Code of Federal Regulations as it relates to an engine uncontrollable high thrust event in combination with a high level of crosswind and a wet or contaminated runway.

[FR Doc. 2017–13733 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–44]

Petition for Exemption; Summary of Petition Received; Charm City Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before July 20, 2017.

ADDRESSES: Send comments identified by docket number {FAA–2017–0379} using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.

• *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Alphonso Pendergrass (202) 267–4713, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Dated: June 26, 2017.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2017–0379.

Petitioner: Charm City Helicopters.

Section(s) of 14 CFR Affected: 99.7.

Description of Relief Sought: The Petitioner requests an exemption for flight operations during the times Terminal Flight Restrictions (TFR) of Notice to Airman 4/3621 (NOTAM 4/3621) is in effect. The exemption, if granted, would allow Charm City Helicopters to operate its helicopters within 3nm of the TFR ring during times the NOTAM is effective.

[FR Doc. 2017–13810 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Dallas/Fort Worth International Airport, Dallas/Fort Worth, Texas

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at the Dallas/Fort Worth International Airport under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before July 31, 2017.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Ben Guttery, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Texas Airports District Office, ASW–650, 10101 Hillwood Parkway, Fort Worth, Texas 76177.

In addition, one copy of any comments submitted to the FAA must

be mailed or delivered to: Mr. Sean Donohue, Chief Executive Officer, Dallas/Fort Worth International Airport, Executive Office, P.O. Box 619428, DFW Airport, Texas 75261.

FOR FURTHER INFORMATION CONTACT: Mr. Steven Cooks, Program Manager, Federal Aviation Administration, Texas Airports District Office, ASW–650, 10101 Hillwood Parkway, Fort Worth, TX 76177, Telephone: (817) 222–5608, email: *Steven.Cooks@faa.gov*, fax: (817) 222–5989.

The request to release property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Dallas/Fort Worth International Airport under the provisions of the AIR 21.

The following is a brief overview of the request:

The Dallas/Fort Worth International Airport requests the release of 41.096 acres of non-aeronautical airport property for permanent easement to the Fort Worth Transportation Authority. The permanent easement to be released will be used for public mass transit improvements and revenues shall be used to further develop, operate and maintain DFW Airport.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at the: Dallas/Fort Worth International Airport, Telephone Number (972) 973–4646.

Issued in Fort Worth, Texas, on 22 June 2017.

Cameron Bryan,

Acting Director, Airports Division.

[FR Doc. 2017–13814 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2017–53]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of the FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before July 20, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0259 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lynette Mitterer, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *Lynette.Mitterer@faa.gov,* phone (425) 227–1047; or Alphonso Pendergrass, ARM–200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, email *alphonso.pendergrass@faa.gov,* phone (202) 267–4713.

This notice is published pursuant to 14 CFR 11.85.

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Staff.

Petition for Exemption

Docket No.: FAA–2017–0259.
Petitioner: The Boeing Company.
Section of 14 CFR Affected: § 25.813(e).
Description of Relief Sought: Allow doors between passenger compartments, for the sole purpose of installing mini-suites in the premium cabin of Boeing Model 777 airplanes.

[FR Doc. 2017–13721 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2017–0002–N–17]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of proposed information collection activities listed below. Before submitting these information collection requests (ICRs) to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in this notice.

DATES: Comments must be received no later than August 29, 2017.

ADDRESSES: Submit written comments on the information collection activities by mail to either: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590; or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–XXXX,'' (the relevant OMB

control number for each ICR is listed below) and should also include the title of the ICR. Alternatively, comments may be faxed to (202) 493–6216 or (202) 493–6497, or emailed to Mr. Brogan at *Robert.Brogan@dot.gov,* or Ms. Toone at *Kim.Toone@dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll free.)

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested parties to comment on the following summary of proposed information collection activities regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques and other forms of information technology (*e.g.,* permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information Federal regulations mandate. In summary, FRA reasons comments received will advance three objectives: (1) Reduce reporting burdens; (2) ensure it organizes information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below is a brief summary of currently approved information collection activities FRA will submit for OMB clearance as the PRA requires:

Title: Railroad Operating Rules.

OMB Control Number: 2130–0035.

Abstract: The collection of information is due to regulations in 49 CFR part 217 which require Class I and Class II railroads to file with FRA copies of their operating rules, timetables, and timetable special instructions, and subsequent amendments. The regulations require Class III railroads to retain copies of these documents at their systems headquarters. Also, 49 CFR 220.21(b) prescribes the collection of information by requiring railroads to retain one copy of their current operating rules with respect to radio communications and one copy of each subsequent amendment. Railroads must make these documents available to FRA upon request. Through these rules, FRA learns the condition of operating rules and practices of trains and instructions railroads provide their employees on operating practices.

Form Number(s): N/A.

Affected Public: Businesses.

Respondent Universe: 755 railroads.

Frequency of Submission: On occasion.

Affected Public: Businesses.

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
217.7—Copy—FRA—Operating rules, timetables, Class I & II RRs.	2 new railroads	2 submissions	1 hour	2 hours.
—Amendments	55 railroads	165 amendments	20 minutes	55 hours.
—Copy of operating rules/timetables, etc. by Class III.	5 new railroads	5 submissions	55 minutes	5 hours.
—Amendments by Class III Railroads	704 railroads	2,013 amendments	15 minutes	503 hours.
217.9—Records of Qualification	755 railroads	4,732 records	2 minutes	158 hours.
—Written Prog. of Operational Tests	5 new railroads	5 programs	9.92 hours	50 hours.
—Records of Operational Tests/Inspections.	755 railroads	9,120,000 records	5 minutes	760,000 hours.
—Amendments	55 railroads	165 amendments	70 minutes	193 hours.
—Quarterly Review of Accident/Incident Data/ Prior Op. Tests/Insp.	37 railroads	148 reviews	2 hours	296 hours.
—Designated Officers & Conduct of 6 Mo. Rev.	37 railroads	37 designations + 74 reviews	5 seconds + 2 hours.	148 hours.
—Designated Officers & Conduct of Six Month Review by Passenger/ Commuter Railroads.	Amtrak + 33 railroads	34 designations + 68 reviews	5 seconds + 2 hours.	136 hours.
—Records of Periodic Reviews	101 railroads	290 review records	1 minute	5 hours.
—Annual Summary on Operational Tests/ Insp.	101 railroads	71 summary records	61 minutes	72 hours.
—FRA Disapproval of RR Program of Operational Tests/Insp. & Response by RR.	755 railroads	5 supporting documents	1 hour	5 hours.
—Amended Prog. Docs	755 railroads	5 amended documents	30 minutes	3 hours.
271.11—Instruction of Program Employees	755 railroads	130,000 instr. employees	8 hours	1,040,000 hours.
—New RR & Copy of Program of Op. Tests.	5 new railroads	5 Programs	8 hours	40 hours.

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
—Amendments to Op. Rules Instr. Program.	755 railroads	110 amendments	30 minutes	55 hours.
218.95—Instruction, Training, Examination—Records.	755 railroads	98,000 records	5 minutes	8,167 hours.
—Response to FRA Disapproval of Program.	755 railroads	5 written/oral submissions	1 hour	5 hours.
—Programs Needing Amendment	755 railroads	5 amended programs	30 minutes	3 hours.
218.97—Employee Copy of Written Procedures.	755 railroads	4,732 copies	6 minutes	473 hours.
—Good Faith Challenges by RR Employees.	98,000 RR Employees	15 challenges	10 minutes	3 hours.
—RR Responses to Empl. Challenge	15 railroads	15 responses	5 minutes	1 hour.
—Immediate Review of Employee Challenge.	15 railroads	5 immediate reviews	30 minutes	3 hours.
—RR Officer Explanation of Federal Law Protection Against Retaliation.	15 railroads	5 explanations	1 minute	.08 hour.
—Documented Protest by RR Employee	10 railroads	10 written protests	15 minutes	3 hours.
—Copies of Protests	10 railroads	10 protest copies	1 minute	.17 hour.
—Further Reviews	10 railroads	3 further reviews	15 minutes	1 hour.
—Written Verification Decision to Employee.	10 railroads	10 verification decisions	10 minutes	2 hours.
—Copy of Written Procedures at RR Hdqtr	755 railroads	755 copies of procedures	5 minutes	63 hours.
—Copy of Verification Decision at RR Headquarters & Division Headquarters.	755 railroads	20 verification decision copies	5 minutes	2 hours.
218.99—Shoving or Pushing Movements.				
—Operating Rule Modifications	755 railroads	32 rule modifications	1 hour	32 hours.
—Locomotive Engineer Job Briefing Before Movement.	130,000 RR Employees	180,000 job briefings	1 minute	3,000 hours.
—Point Protection Determinations & Signals/Instructions to Control Movements.	130,000 RR Employees	87,600,000 determinations + 87,600,000 signals/instructions.	1 minute + 1 minute.	2,920,000 hours.
—Remote Control Movements—Verbal Confirmation.	130,000 RR Employees	876,000 confirmations	1 minute	14,600 hours.
—Remote Control Determinations That Zone Is Not Jointly Occupied/Track Clear.	130,000 RR Employees	876,000 confirmations	1 minute	14,600 hours.
—Dispatcher Authorized Train Movements	6,000 RR Dispatchers	30,000 auth. movements	1 minute	500 hours.
218.101—Operating Rule Re: Leaving Rolling & On-Track MOW Equipment in the Clear.	755 railroads	32 amended op. rules	30 minutes	16 hours.
218.103—Hand-Operated Switches—RR Operating Rule That Complies w/ § 218.103.	755 railroads	32 modified operating rules	1 hour	32 hours.
—Specification of Minimum Job Briefing Requirements.	755 railroads	5 modified op. rules	30 minutes	3 hours.
—Employee Operating or Verifying Position of Hand-operated Switches: Job Briefings.	755 railroads	1,125,000 job briefings	1 minute	18,750 hours.
218.105—Additional Requirements for Hand-Operated Main Track Switches—Job Briefing.	755 railroads	60,000 job briefings	1 minute	1,000 hours.
—Roadway Worker Report on Position of Switches to Roadway Worker in Charge (RWIC) or Designated Employee Conveying Information to RWIC.	7704 railroads	100,000 empl. reports + 100,000 conveyances.	1 minute + 1 minute.	3,334 hours.
—Dispatcher Acknowledgment of Switch Position and Employee Confirmation to Train Dispatcher.	755 railroads	60,000 acknowledgment + 60,000 confirmations.	30 seconds + 5 seconds.	583 hours.
218.109—Hand-Operated Fixed Derails: Job Briefings.	755 railroads	562,500 job briefings	30 seconds	4,688 hours.

Total Responses: 188,591,125.

Total Estimated Annual Burden: 4,797,590 hours.

Type of Request: Extension with change of a currently approved ICR (extension with change reflects revised estimates for some rule requirements).

Title: Track Safety Standards; Concrete Crossties.

OMB Control Number: 2130–0592.

Abstract: On April 1, 2011, FRA amended the Federal Track Safety Standards to promote the safety of railroad operations over track constructed with concrete crossties. FRA mandated specific requirements for effective concrete crossties, for rail fastening systems connected to concrete crossties, and for automated inspections of track constructed with concrete crossties. FRA uses the information collected under 49 CFR 213.234 to ensure automated track inspections of track constructed with concrete crossties are carried out as specified in the rule to supplement visual inspections by Class I and Class II railroads, intercity passenger railroads, and commuter railroads or small

government jurisdictions that serve populations greater than 50,000.

Form Number(s): N/A.

Affected Public: Businesses.

Respondent Universe: 18 railroads

Frequency of Submission: On occasion.

Reporting Burden:

CFR Section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
213.234—Automated Inspection of Track Constructed with Concrete Crossties: Exception Reports Listing All Exception to § 213.109(d)(4).	18 Railroads	75 reports	8 hours	600 hours.
—Copies of Exception Report Provided to Designated Person under § 213.234(e)(1).	18 Railroads	75 report copies	12 minutes	15 hours.
—Field Verification of Exception Reports	18 Railroads	75 verification	2 hours	150 hours.
—Records of Inspection Data	18 Railroads	75 records	30 minutes	38 hours.
—Institution of Procedures by Track Owner to Maintain Integrity of Track Data Collected by the Measurement System.	18 Railroads	18 procedures	4 hours	72 hours.
—Training by Track Owner: Annual Training in Handing Rail Seat Deterioration Exceptions to All Persons Designated Fully Qualified under § 213.7.	18 Railroads	2,000 trained employees	2 hours	4,000 hours.

Total Responses: 2,318

Total Estimated Annual Burden: 4,875 hours

Type of Request: Extension with change of a currently approved ICR (extension with change reflects revised estimates for some rule requirements)

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Sarah L. Inderbitzin,

Acting Chief Counsel.

[FR Doc. 2017–13746 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0107]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SEA RAVEN; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0107. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SEA RAVEN is:

—*Intended Commercial Use of Vessel:* ''Sports Fishing-fish caught are not sold commercially''

—*Geographic Region:* ''California''

The complete application is given in DOT docket MARAD–20170107 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

By Order of the Maritime Administrator.

Dated: June 22, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13811 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0114]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FRIDAY; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0114. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FRIDAY is:

—*Intended Commercial Use of Vessel:* ''Occasional day and short-term charters predominately in South Florida, and in various other areas of Florida''

—*Geographic Region:* ''Florida''

The complete application is given in DOT docket MARAD–2017–0114 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121

* * * * *

By Order of the Maritime Administrator.

Dated: June 26, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13817 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0108]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel TRAVELER; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0108. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TRAVELER is:

—*Intended Commercial Use of Vessel:* Sailboat charters

—*Geographic Region:* ''Washington State''

The complete application is given in DOT docket MARAD–2017–0108 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver

criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

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By Order of the Maritime Administrator.
Dated: June 22, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13809 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0109]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GATO GORDO; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0109. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GATO GORDO is:

—INTENDED COMMERCIAL USE OF VESSEL: ''6 pack charters and pleasure cruises''

—GEOGRAPHIC REGION: ''California''

The complete application is given in DOT docket MARAD–2017–0109 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

By Order of the Maritime Administrator.
Dated: June 22, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13822 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0111]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MARBELLA; Invitation for Public Comments

AGENCY: Maritime Administration

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0111. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MARBELA is:

—*Intended Commercial Use of Vessel:* ''Private Vessel Charters, Passengers Only''

—*Geographic Region:* ''Florida, California, Oregon, Washington, and Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound]).''

The complete application is given in DOT docket MARAD–2017–0111 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

By Order of the Maritime Administrator.

Dated: June 22, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13826 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0106]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PRINCESS DONNA; Invitation for Public Comments

AGENCY: Maritime Administration

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0106. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PRINCESS DONNA is:

—INTENDED COMMERCIAL USE OF VESSEL: ''carry passengers only''

—GEOGRAPHIC REGION: ''Florida''

The complete application is given in DOT docket MARAD–2017–0106 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

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By Order of the Maritime Administrator.

Dated: June 22, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13813 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0112]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MARIE KNIGHT; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief

description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0112. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MARIE KNIGHT is:

—*Intended Commercial Use of Vessel:* ''Pleasure charter, sightseeing, sunset cruise and anchoring for swimming/picnic. No fishing and no whale watching.''

—*Geographic Region:* ''Massachusetts''

The complete application is given in DOT docket MARAD–2017–0112 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

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By Order of the Maritime Administrator.

Dated: June 22, 2017.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2017–13828 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2017–0115]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HYP NAUTIC; Invitation for Public Comments

AGENCY: Maritime Administration

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 31, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2017–0115. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HYP NAUTIC is:

—*Intended Commercial Use of Vessel:* ''Charter Fishing, Whale watching and Water Taxi''

—*Geographic Region:* ''Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])''

The complete application is given in DOT docket MARAD–2017–0115 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact

the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

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By Order of the Maritime Administrator.
Dated: June 26, 2017.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2017–13816 Filed 6–29–17; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Funding Opportunity Title: Notice of Funds Availability Inviting Applications for the Fiscal Year 2017 Funding Round of the Capital Magnet Fund (CMF)

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2017–CMF.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.011.

Key Dates:

TABLE 1—FY 2017 CMF PROGRAM FUNDING ROUND—CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
SF–424 Mandatory form	July 28, 2017	11:59 p.m. ET	Electronically via *Grants.gov.*
Last day to contact CMF Program Staff	August 29, 2017	5:00 p.m. ET	Service Request via Awards Management Information System (AMIS) or CDFI Fund Helpdesk: 202–653–0421 or *cmf@cdfi.treas.gov.*
CMF Application and Required Attachments	August 31, 2017	5:00 p.m. ET	Electronically via Awards Management Information System (AMIS).

Executive Summary: The Capital Magnet Fund (CMF) is administered by the Community Development Financial Institutions Fund (CDFI Fund). Through the CMF, the CDFI Fund provides financial assistance grants to Community Development Financial Institutions (CDFIs), and to qualified Nonprofit Organizations that have the development or management of affordable housing as one of their principal purposes. All awards provided through this Notice of Funds Availability (NOFA) are subject to funding availability.

I. Program Description

A. *Authorizing Statute and Regulation:* The CMF was established through the Housing and Economic Recovery Act of 2008 (HERA), which added section 1339 to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992. For a complete understanding of the program, the CDFI Fund encourages Applicants to review the CMF interim rule (12 CFR part 1807) as amended February 8, 2016 (the CMF Interim Rule), this NOFA, the environmental quality regulation (12 CFR part 1815), the CMF funding application (referred to hereafter as the ''Application,'' meaning the application submitted in response to this NOFA), and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200; 78 FR 78590) (Uniform Administrative Requirements or UAR). Each capitalized term used in this NOFA, but not defined herein, shall have the respective meanings assigned to them in the CMF Interim Rule, the Application, or the Uniform Administrative Requirements. Details regarding Application content requirements are found in the Application and related materials at *www.cdfifund.gov/cmf.*

B. *History:* The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. Since its creation in 1994, the CDFI Fund has awarded nearly $2.6 billion to CDFIs, community development organizations, and financial institutions through the CMF, Community Development Financial Institutions Program (CDFI Program), the Native American CDFI Assistance Program (NACA Program), the Bank Enterprise Award Program (BEA Program), and the Financial Education and Counseling Pilot Program. In addition, the CDFI Fund has allocated more than $50.5 billion in tax credit allocation authority through the New Markets Tax Credit Program (NMTC Program) and has obligated $1.1 billion in bond guarantees to Qualified Issuers and Eligible CDFIs through the CDFI Bond Guarantee Program.

C. *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200):* The Uniform Administrative Requirements codify financial, administrative, procurement, and program management standards that Federal award-making agencies must follow. Per the Uniform Administrative Requirements, when evaluating award applications, awarding agencies must evaluate the risks to the program posed by each Applicant, and each Applicant's merits and eligibility. These requirements are designed to ensure that Applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, history of performance, and single audit findings. In addition, the Uniform Administrative Requirements include guidance on audit requirements and other award compliance requirements for award Recipients.

D. *Priorities:* The purpose of the CMF is to attract private capital for and increase investment in the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Extremely Low-Income, Very Low-Income, and Low-Income Families, as well as Economic Development Activities, which, In Conjunction With Affordable Housing Activities, implement a Concerted Strategy to stabilize or revitalize a Low-Income Area or Underserved Rural Area. In the FY 2017 funding round, the CDFI Fund will implement these priorities by funding: (i) Applications where a minimum of 20 percent of all Affordable Housing rental units that will be financed and/or supported with FY 2017 CMF Award dollars are targeted to Very Low-Income Families and a minimum of 20 percent of all Affordable Housing homeownership units that will

be financed and/or supported with FY 2017 CMF Award dollars are targeted to Low-Income Families; and (ii) Applications that leverage a higher amount of private capital to finance and/or support Affordable Housing Activities and Economic Development Activities. Additionally, the CDFI Fund seeks to fund Applications serving geographically diverse areas of economic distress, including Metropolitan Areas and Underserved Rural Areas.

E. *Funding limitations:* The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA.

II. Federal Award Information

A. *Funding Availability:* The CDFI Fund plans to make $119.5 million in awards for the CMF FY 2017 round under this NOFA. HERA prohibits the CDFI Fund from obligating more than 15 percent of the aggregate available CMF funding to any Applicant, its Subsidiaries and Affiliates in the same funding round. Affiliated entities are not allowed to apply separately under this NOFA. To provide an example of the size of awards in past CMF funding rounds, the CDFI Fund notes that in FY 2016 CMF round the statutory cap was $13.7 million, but the largest amount awarded was $5.5 million. Moreover, given administrative and compliance responsibilities for award Recipients, the CDFI Fund will not accept Applications in the FY 2017 round that request less than $500,000 and will not provide awards below $500,000 to any Applicant receiving an award in the FY 2017 CMF Round.

The CDFI Fund reserves the right, in its sole discretion, to provide a CMF Award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application. An Applicant may receive only one award through the FY 2017 CMF Program Funding Round.

B. *Types of Awards:* The CDFI Fund will provide CMF Awards in the form of grants. CMF Awards must be used to support the eligible activities as set forth in 12 CFR 1807.301. CMF Awards cannot be ''passed through'' to third-party entities, whether Affiliates, Subsidiaries, or others, to undertake the eligible activities set forth in 12 CFR 1807.301, without the prior written approval of the CDFI Fund.

C. *Limitations on using CMF Awards in conjunction with other CDFI Fund awards/allocations:* 1. A CMF Award Recipient may not use its CMF Award and awards/allocations from other CDFI Fund programs to finance activities in the same property unless the CMF Award dollars are used to finance/support a different ''phase'' of development than what is funded by other CDFI Fund program awards/allocations. The separate phases of development financing are considered to be: (1) Predevelopment; (2) acquisition; (3) site work (preconstruction); (4) construction/rehabilitation; (5) permanent financing; or (6) bridge financing between two or more phases. If the Recipient has received multiple CMF Awards, these awards are not subject to this phasing restriction and may be combined in the same Project phase. The term Recipient includes the CMF Award Recipient and any Affiliates.

If providing Homeownership assistance, a CMF Award may be used in conjunction with awards/allocations from other CDFI Fund programs only if the Project can be divided into such phases, and the CMF Award is used in a different phase from the other CDFI Fund program awards/allocations. To clarify, a CMF Award cannot be used for a Homeownership property that is permanently financed (or supported) by both the Recipient's CMF Award and an award/allocation from another CDFI Fund program (*e.g.,* down payment assistance funded from CMF dollars may not be combined with a permanent mortgage funded from another CDFI Fund program).

2. Costs financed/supported by the Recipient's other awards/allocations from CDFI Fund programs, including awards from prior CMF rounds, may not be counted or reported as Leveraged Costs for the CMF Award, as further set forth in the Assistance Agreement. While the Recipient's other CMF Awards may be used to finance/support the same property, each award must separately meet the program requirements as outlined in the applicable Assistance Agreement and the CMF interim rule (12 CFR part 1807). The term Recipient includes the CMF Award Recipient and any Affiliates.

In all cases, the CMF Award remains subject to the following restriction imposed by the CDFI Bond Guarantee Program: Award funds received under any CDFI Fund program cannot be used by any participant of the CDFI Bond Guarantee Program, including Qualified Issuers, Eligible CDFIs, and Secondary Borrowers, to pay principal, interest, fees, administrative costs, or issuance costs (including Bond Issuance Fees) related to the CDFI Bond Guarantee Program, or to fund the Risk Share Pool for a Bond Issue (all capitalized terms used in this sentence, other than ''CMF Award'', shall have the meanings ascribed to them in the CDFI Bond Guarantee Program regulations and applicable guidance).

D. *Anticipated Start Date and Period of Performance:* The CDFI Fund anticipates the period of performance for the FY 2017 CMF Program Funding Round to begin in late 2017/early 2018. The period of performance for each CMF Award begins with the date that the CDFI Fund announces the Recipients of CMF Awards and continues until the end of the ten-year period of affordability, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement, during which time the Recipient must meet certain performance goals.

E. *Eligible Activities:* A CMF Award must support or finance activities that attract private capital for and increase investment in (i) the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Low-, Very Low- and Extremely Low-Income Families, and (ii) Economic Development Activities. CMF Awards may only be used as follows: (i) to provide Loan Loss Reserves, (ii) to capitalize a Revolving Loan Fund, (iii) to capitalize an Affordable Housing Fund, (iv) to capitalize a fund to support Economic Development Activities, (v) for Risk-Sharing Loans, or (vi) to provide Loan Guarantees. No more than 30 percent of a CMF Award may be used for Economic Development Activities. For the FY 2017 CMF Round, the CDFI Fund will allow all Recipients to use up to 5 percent of their CMF Award for Direct Administrative Expenses. The amount available for Direct Administrative Expenses may only be used for direct costs (as defined by the Uniform Administrative Requirements) incurred by the Recipient and related to the financing and/or support of a Project. The CDFI Fund considers the tracking of impacts and outcomes associated with Projects financed and/or supported by a CMF Award to fall under Direct Administrative Expenses. Any portion of the amount available for Direct Administrative Expenses may be used for direct costs related to the effective tracking and evaluation of program or evidence-based outcomes for CMF-funded Projects.

III. Eligibility Information

A. Eligible Applicants: In order to be eligible to apply for a CMF Award, an Applicant must either be a Certified CDFI or a Nonprofit Organization, as defined in 12 CFR 1807.104. Table 2

indicates the criteria that each entity type must meet in order to be eligible for a CMF Award pursuant to this NOFA. Note: A Certified CDFI that is also a Nonprofit Organization only needs to meet the Certified CDFI eligibility criteria described in Table 2, below, in order to be eligible for a CMF Award.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS

Category	Eligibility requirements
Certified CDFI	☐ Has been in existence as a legally formed entity for at least 3 years prior to the AMIS Application deadline under this NOFA; ☐ Has been determined by the CDFI Fund to meet the CDFI certification requirements set forth in 12 CFR 1805.201 and as verified in the CDFI's AMIS account as of the date of this NOFA; and ☐ Has not been notified by the CDFI Fund that its certification is in default or has been terminated. ☐ In cases where the CDFI Fund has provided a Certified CDFI with written notification that it no longer meets one or more certification standards and has been given an opportunity to cure, the CDFI Fund will continue to consider this Applicant to be a Certified CDFI until it has received a final determination that its certification has been terminated.
Nonprofit Organization	☐ Has been in existence as a legally formed entity for at least 3 years prior to the AMIS Application deadline under this NOFA; ☐ Demonstrates, through articles of incorporation, by-laws, or other board-approved documents, that the development or management of affordable housing are among its principal purposes; and ☐ Demonstrates that at least thirty-three and one-third percent of its total assets are dedicated to the development or management of affordable housing.
Application type and submission overview through *Grants.gov* and Awards Management Information System (AMIS).	☐ All Applicants must submit the required Application documents listed in Table 4. ☐ The CDFI Fund will only accept Applications that use the official application templates provided on the *Grants.gov* and AMIS websites. Applications submitted with alternative or altered templates will not be considered. ☐ All Applicants must submit the required documents in two locations: (1) *Grants.gov* and (2) AMIS. ○ *Grants.gov:* Applicants must submit the OMB SF–424 Mandatory (Application for Federal Assistance) form. ○ AMIS: Applicants must submit all other required Application materials. ○ All Applicants must register in the *Grants.gov* and AMIS systems to submit an Application successfully. The CDFI Fund strongly encourages Applicants to register as early as possible. ☐ *Grants.gov* and the SF–424 Mandatory form: ○ The SF–424 must be submitted in *Grants.gov* before the other Application materials are submitted in AMIS. Applicants are strongly encouraged to submit their SF–424 as early as possible via the *Grants.gov* portal. ○ Because the SF–424 is part of the Application, if the SF–424 is not accepted by *Grants.gov*, the CDFI Fund will not review any materials submitted in AMIS and the Application will be deemed ineligible. ☐ AMIS: ○ AMIS is the CDFI Fund's enterprise-wide information technology system that will be used to submit and store organization and Application information with the CDFI Fund. ○ Applicants are only allowed one submission in AMIS.
Employer Identification Number (EIN).	☐ All Applicants must have a unique EIN assigned by the Internal Revenue Service. ☐ The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization.
DUNS number	☐ Pursuant to OMB guidance (68 FR 38402), each Applicant must apply using its unique DUNS number in *Grants.gov*. ☐ The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization.
Awards Management Information System (AMIS).	☐ Each Applicant must register as an organization in AMIS and submit all required Application materials through the AMIS portal. ☐ The Authorized Representative must be included as a ''user'' in the Applicant's AMIS account. ☐ An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or not be able to successfully submit an Application.
501(c)(4) status	☐ Pursuant to 2 U.S.C. 1611, any 501(c)(4) organization that engages in lobbying activities is not eligible to apply for or receive a CMF Award.
Compliance with Nondiscrimination and Equal Opportunity Statutes, Regulations, and Executive Orders.	☐ An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination within the last 3 years as of the date of the NOFA indicates the Applicant has violated any of the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C.2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107); Title VIII of the Civil Rights Act of 1968, as amended (42 U.S.C. 3601 et seq.); and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.

Any Applicant that does not meet the criteria in Table 2 is ineligible to apply for a CMF Award under this NOFA. Further, Section III.B describes additional considerations applicable to prior award Recipients and/or Allocatees under any CDFI Fund program.

B. Prior award Recipients and/or Allocatees: Applicants must be aware that success in a prior round of any of the CDFI Fund's programs is not indicative of success under this NOFA. Prior award Recipients and/or Allocatees under any CDFI Program are eligible to apply under this NOFA, except as noted in Table 3:

TABLE 3—ELIGIBILITY REQUIREMENTS FOR APPLICANTS WHICH ARE PRIOR AWARD RECIPIENTS

Criteria	Description
Pending resolution of noncompliance.	The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues if the CDFI Fund has not yet made a final compliance determination.
Noncompliance status	☐ The CDFI Fund will not consider an Application submitted by an Applicant that has a previously executed award agreement(s) if, as of the date of the NOFA, (i) the CDFI Fund has made a determination that such entity is noncompliant with a previously executed agreement and (ii) the CDFI Fund has provided written notification that such entity is ineligible to apply for or receive any future CDFI Fund awards or allocations. Such entities will be ineligible to submit an Application for such time period as specified by the CDFI Fund in writing. ☐ The CDFI Fund will not consider any Applicant that has defaulted on a CDFI program loan within five years of the AMIS Application deadline.

C. Contacting the CDFI Fund: Accordingly, Applicants that are prior Recipients and/or Allocatees under any CDFI Fund program are advised to: (i) Comply with requirements specified in an Assistance Agreement, award agreement, allocation agreement, bond loan agreement, or agreement to guarantee. All outstanding reporting and compliance questions should be directed to the Certification, Compliance Monitoring, and Evaluation help desk by AMIS Service Requests or by telephone at (202) 653–0421. The CDFI Fund will not respond to Applicants' reporting, compliance, or disbursement telephone calls or email inquiries that are received after 5:00 p.m. ET on August 29, 2017 until after the Application deadline. The CDFI Fund will respond to technical issues related to AMIS Accounts through 5:00 p.m. ET on August 31, 2017, via AMIS Service Requests, or at *AMIS@cdfi.treas.gov,* or by telephone at (202) 653–0422.

D. Cost sharing or matching funds requirements: Not applicable.

E. Other Eligibility Criteria:

1. Debarment/Do not pay verification: The CDFI Fund will conduct a debarment check and will not consider an Application if the Applicant is delinquent on any Federal debt or otherwise ineligible to receive a Federal award. The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government and provides delinquency information to the CDFI Fund to assist with the debarment check.

2. Entities that Submit Applications Together with Affiliates: As part of the Application review process, the CDFI Fund considers whether Applicants are Affiliates, as such term is defined in 12 CFR1807.104. If an Applicant and its Affiliates wish to submit Applications, they must do so collectively, in one Application; an Applicant and its Affiliates may not submit separate Applications. If Affiliates submit multiple or separate Applications, the CDFI Fund will reject all such Applications received.

Furthermore, an Applicant that receives an award in this CMF round may not become an Affiliate of another Applicant that receives an award in this CMF round at any time after the submission of a CMF Application under this NOFA. This requirement will also be a term and condition of the Assistance Agreement (see additional Application guidance materials on the CDFI Fund's Web site at *http://www.cdfifund.gov/cmf* for more details).

3. An Applicant will not be eligible to receive a CMF Award if the Applicant fails to demonstrate in the Application that its CMF Award would result in Eligible Project Costs (Leveraged Costs plus those costs funded by the CMF Award) that equal at least 10 times the amount of the CMF Award. Note that no costs attributable to Direct Administrative Expenses may be considered Eligible Project Costs.

IV. Application and Submission Information

A. Address to Request Application Package: Application materials can be found on the *Grants.gov* and the CDFI Fund's Web site at *www.cdfifund.gov/cmf.* Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk by email at *cmf@cdfi.treas.gov* or by phone at (202) 653–0421.

B. Content and Form of Application Submission: The CDFI Fund will post to its Web site, at *www.cdfifund.gov/cmf,* instructions for accessing and submitting an Application. Detailed Application content requirements are found in the Application and related guidance documents. All Applications must be prepared in English and calculations must be made in U.S. dollars. Table 4 lists the required funding Application documents for the FY 2017 CMF Program Funding Round. Applicants must submit all required documents for the Application to be deemed complete. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically requested will not be reviewed or considered as part of the Application. Information submitted must accurately reflect the Applicant's activities.

TABLE 4—FUNDING APPLICATION DOCUMENTS

Application document	Submission format	Required?
Standard Form (SF) 424 Mandatory Form	Fillable PDF in *Grants.gov*	Required for all Applicants.
CMF Application	AMIS	Required for all Applicants.
Attachments to the Application		
Audited financial statements (most recent 2 fiscal years)	PDF in AMIS	Required for all Applicants.
Any management letters related to the audited financial statements (most recent 2 fiscal years).	PDF in AMIS	Required for all Applicants.

TABLE 4—FUNDING APPLICATION DOCUMENTS—Continued

Application document	Submission format	Required?
State Charter, Articles of Incorporation, or other establishing documents designating that the Applicant is a nonprofit or not-for-profit entity under the laws of the organization's State of formation.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.
A certification demonstrating tax exempt status from the IRS. For Applicants that are governmental instrumentalities only, and as long as all other eligibility requirements are met, the CDFI Fund will accept a legal opinion from counsel, in form and substance acceptable to the CDFI Fund, opining that the Applicant is exempt from federal taxation.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.
Articles of incorporation, by-laws or other documents demonstrating that the Applicant has a principal purpose of managing or developing affordable housing.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.

The CDFI Fund has a sequential, two-step process that requires the submission of Application documents in separate systems and on separate deadlines. The SF–424 form must be submitted through *Grants.gov* and all other application documents through the AMIS portal. The CDFI Fund will not accept Applications via email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved by the CDFI Fund. The separate application deadlines for the SF–424 and all other Application materials are listed in Tables 1 and 5. Only the Authorized Representative or Application Point of Contact designated in AMIS may submit the Application through AMIS.

Applicants are strongly encouraged to submit the SF–424 as early as possible through *Grants.gov* to provide sufficient time to resolve any submission problems. Applicants should contact *Grants.gov* directly with questions related to the registration or submission process as the CDFI Fund does not administer the *Grants.gov* system.

The CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as soon as possible as it may take several weeks to complete (refer to the following link: *http://www.grants.gov/web/grants/register.html*). An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active.

C. Dun and Bradstreet Data Universal Numbering System (DUNS): Pursuant to the Uniform Administrative Requirements, each Applicant must provide as part of its Application submission, a valid Dun & Bradstreet Data Universal Numbering System (DUNS) number. Any Applicant without a DUNS number will not be able to register and submit an Application in the *Grants.gov* system. Please allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

D. System for Award Management (SAM): Any entity applying for Federal grants or other forms of Federal financial assistance through *Grants.gov* must be registered in SAM before submitting its Application materials through that platform. The SAM registration process can take several weeks to complete. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active. Each Applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will not consider any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit its Application by the Application deadline. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system. For more information about SAM, please visit *https://www.sam.gov.*

E. *Submission Dates and Times:*

1. Submission Deadlines: Table 5 lists the deadlines for submission of the documents related to the FY 2017 CMF Program Funding Round:

TABLE 5—FY 2017 CMF DEADLINES FOR APPLICANTS

Document	Deadline	Time—eastern time (ET)	Submission method
SF–424 Mandatory form	July 28, 2017	11:59 pm ET	Electronically via *Grants.gov.*
CMF Application and Required Attachments.	August 31, 2017	5:00 pm ET	Electronically via AMIS.

2. Confirmation of Application Submission in *Grants.gov* and AMIS: Applicants are required to submit the OMB SF–424 Mandatory (Application for Federal Assistance) form through the *Grants.gov* system and must submit all other required Application materials through the AMIS Web site. Application materials submitted through each system are due by the applicable deadline listed in Table 5. Applicants must submit the SF–424 by an earlier deadline than that of the other required application materials in AMIS. If the SF–424 is not successfully submitted through *Grants.gov* by the corresponding deadline, the CDFI Fund will not review any of the materials submitted in AMIS, and the Application will be deemed ineligible. Thus, Applicants are strongly encouraged to submit the SF–424 as early as possible in the *Grants.gov* portal since submission problems may impact the ability to submit the overall Application.

(a) *Grants.gov* Submission Information: Each Applicant will receive an email from *Grants.gov* immediately after submitting the SF–424 confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for

the submitted SF–424. Within 48 hours, the Applicant will receive a second email which will indicate if the submitted SF–424 was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their SF–424 was validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their SF–424 by contacting the helpdesk at *Grants.gov* directly. The Application materials submitted in AMIS are not officially accepted by the CDFI Fund until *Grants.gov* has validated the SF–424. If using the *Grants.gov* Workspace function, please note that the Application package has not been submitted if you have not received a tracking number.

(b) Award Management Information System (AMIS) Submission Information: AMIS is a web-based portal where Applicants will directly enter their Application information and add required attachments listed in Table 4. AMIS will verify that the Applicant provided the minimum information required to submit an Application. Applicants are responsible for the quality and accuracy of the information and attachments included in the Application submitted in AMIS. The CDFI Fund strongly encourages the Applicant to allow sufficient time to confirm the Application content, review the material submitted, and remedy any issues prior to the Application deadline. Applicants can only submit one Application in AMIS. Upon submission, the Application will be locked and cannot be resubmitted, edited, or modified in any way. The CDFI Fund will not unlock or allow multiple Application submissions.

3. Multiple Application Submissions: If an Applicant submits multiple SF–424 Applications in *Grants.gov*, the CDFI Fund will only review the last SF–424 Application submitted in *Grants.gov*. Applicants may only submit one Application through AMIS.

4. Late Submission: The CDFI Fund will not accept an Application submitted after the applicable *Grants.gov* or AMIS Application deadline, except where the submission delay was a direct result of a Federal government administrative or technological error. This exception includes any errors associated with *Grants.gov*, *SAM.gov*, AMIS or any other applicable government system. Please note that this exception does not apply to errors arising from obtaining a DUNS number from Dun & Bradstreet, which is not a government entity. An Applicant unable to make timely submission of its Application due to any errors in the process of obtaining a DUNS number will not be allowed to submit its Application after the application deadline has passed. In the event of a government administrative or technological error causing delay, the Applicant must submit a request for acceptance of late Application submission and include documentation of the error no later than two business days after the applicable Application deadline. The CDFI Fund will not respond to requests for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests via Service Request in AMIS with the subject line of ''FY2017 CMF: Late Application Submission Request.''

5. Intergovernmental Review: Not Applicable.

6. Funding Restrictions: CMF Awards are limited by the following:

(a) A Recipient shall use CMF Award funds only for the eligible activities set forth in 12 CFR 1807.301 and as described in Section II.C and Section II.E of this NOFA and its Assistance Agreement.

(b) A Recipient may not disburse CMF Award funds to an Affiliate, Subsidiary, or any other entity without the CDFI Fund's prior written approval.

(c) CMF Award Payment shall only be made to the Recipient.

(d) The CDFI Fund, in its sole discretion, may pay CMF Awards in amounts, or under terms and conditions, which are different from those requested by an Applicant.

7. Other Submission Requirements: Each Applicant must register as an organization in AMIS in order to submit the required Application materials through this portal. The Authorized Representative and/or application point(s) of contact must be included as ''Contacts'' in the Applicant's AMIS account. The Authorized Representative must also be a ''user'' in AMIS and must electronically sign the Application prior to submission through AMIS. An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or fail to submit an Application successfully. After submitting its Application, the Applicant will not be permitted to revise or modify its Application in any way or attempt to negotiate the terms of an award.

V. Application Review Information

A. *Criteria:* All complete and eligible Applications will be reviewed in accordance with the criteria and procedures described in the CMF Interim Rule, this NOFA, the Application guidance, and the Uniform Administrative Requirements. As part of the review process, the CDFI Fund reserves the right to contact the Applicant by telephone, email, mail, or through an on-site visit for the sole purpose of clarifying or confirming Application information at any point during the review process. The CDFI Fund reserves the right to collect such additional information from Applicants as it deems appropriate. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or its Application may be rejected. For the sake of clarity, specific application evaluation criteria are described in the context of the overall application review and selection process described in Section V.B. below.

B. *Review and Selection Process:*

The CDFI Fund will evaluate each complete and eligible Application using the multi-phase review process described in this Section.

1. Quantitative Assessment: Each complete and eligible Application will receive a numeric score based on the responses to quantitative questions in the Application. Applications may receive a score of up to 100 points based on the following factors outlined in Table 6.

TABLE 6—QUANTITATIVE ASSESSMENT FACTORS

Section	Points	Assessment criteria
Business and Leveraging Strategy ..	40	• Private leverage multiplier, including the portion from 3rd parties.
	.....	• Reasonableness of projected activities based on track record.
	.....	• Applicant-level leverage multiplier.
Community Impact	35	• Percent of rental housing units targeted to Very Low-Income or below (50% of AMI or below).

TABLE 6—QUANTITATIVE ASSESSMENT FACTORS—Continued

Section	Points	Assessment criteria
	.....	• Percent of homeownership units targeted to Low-Income or below (80% of AMI or below).
	.....	• Commitment to only finance Economic Development Activities in Low-Income Areas.
	.....	• Percent of housing units to be produced in Areas of Economic Distress.
Financial Health	25	• Capitalization.
	.....	• Operating Performance.
	.....	• Net income.
	.....	• Liquidity.
	.....	• Audit Results.

Within the Business and Leveraging Strategy Section of the Quantitative Assessment, an Applicant will generally score more favorably to the extent it: Is leveraging a high multiplier of private capital, particularly third party capital; has a proven track record; and is leveraging some portion of capital at the Applicant-level.

Within the Community Impact Section, an Applicant will generally score more favorably to the extent that it: Commits to producing a higher percentage of rental housing units targeted to Very Low-Income Families (if proposing to use CMF for rental housing); commits to producing a higher percentage of homeownership units targeted to Low-Income Families (if proposing to use CMF for homeownership); commits to only financing Economic Development Activities in Low-Income Areas (if proposing to use CMF for economic development); and commits to producing a higher percentage of units in Areas of Economic Distress. Areas of Economic Distress are census tracts: (a) Where at least 20 percent of households that are Very Low-Income (50% of AMI or below) spend more than half of their income on housing; or (b) where the unemployment rate is at least 1.5 times the national average; or (c) that are Low-Income Housing Tax Credit Qualified Census Tracts; or (d) where greater than 20 percent of households have incomes below the poverty rate and the rental vacancy rate is at least 10 percent; or (e) where greater than 20 percent of the households have incomes below the poverty rate and the homeownership vacancy rate is at least 10 percent; or (f) Are Underserved Rural Areas as defined in the CMF Interim Rule (as amended February 8, 2016; 12 CFR part 1807). Within the Financial Health section, Applicants will generally score more favorably to the extent that their 3-year financial data indicates: Strong capitalization, operating performance, and liquidity; positive net income; and that the Applicant has not had any negative results (*e.g.* opinion other than unqualified; a ''going concern paragraph;'' repeat finding of reportable conditions; material weaknesses in internal control) in any of the three most recently completed annual audits.

Once the quantitative score is determined, Applicants will be grouped into two categories: (1) Those with a maximum Non-Metropolitan Area investment of 50 percent or greater and (2) all other Applicants. Applicants in each category will be ranked in descending order based on their quantitative review score. The top 75 percent of Applications in each category will be forwarded to the next level of review: External Application Review. The CDFI Fund reserves the right to forward additional Applications to the External Application Review phase in order to ensure that a diversity of geographies are served by the Applicants reviewed in the External Application Review phase. The CDFI Fund also reserves the right not to implement the Quantitative Assessment if it receives fewer than 140 CMF Applications.

2. External Application Review: Applications that advance from the Quantitative Assessment will be separately scored by more than one external non-Federal reviewer who are selected based on criteria that include: A professional background in affordable housing and community and economic development finance with extensive background in affordable housing. These reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. Reviewers will be assigned a set number of Applications to review. The reviewer will provide a score for each of the Applications assessed in accordance with the scoring criteria outlined in Section V.B.2 of this NOFA and the Application materials.

The external reviewer's evaluation will result in the Application being awarded up to 100 total points by each reviewer. These points will be distributed across three sections: Business and Leveraging Strategy (40 possible points), Community Impact (35 possible points), and Organizational Capacity (25 possible points). An Applicant's final External Application review score will be a composite based on the external reviewers' evaluation and Quantitative Assessment factors. The majority of the score will be based on the external reviewers' evaluation.

(a) Business and Leveraging Strategy (40 points): In the Business and Leveraging Strategy section, the Applicant will address: (i) The needs of communities and persons in its proposed Service Area(s) and the extent to which the proposed strategy addresses these needs; (ii) the affordable housing and financing gaps addressed by its business strategy; (iii) the projected CMF activities and track record; (iv) plans to incorporate a CMF Award into project finance; (v) its strategy for leveraging private capital with a CMF Award, particularly third-party capital; and (vi) its strategy for leveraging its CMF Award at the Enterprise-level and/or through re-investments (if applicable).

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it: (i) Clearly aligns its proposed CMF Award activities with the affordable housing and financing gaps it identifies; (ii) demonstrates that its projected activities are achievable based on the Applicant's strategy and track record; (iii) describes a clear process for locating projects and proposes activities that have a clear need for CMF financing; (iv) has a clear strategy for and track record of leveraging private capital; and (v) has a clear strategy for and demonstrates a track record of leveraging funds at the enterprise-level and/or through re-investments (if applicable).

(b) Community Impact (35 points): In the Community Impact Section, the Applicant will address: (i) Projected outcomes and impacts of Affordable Housing Activities and Economic Development Activities; (ii) its strategy and track record of producing housing

units targeted to Low-Income Families (for homeownership) and to Very Low-Income Families (for rental); (iii) if applicable, its strategy and track record of financing and/or supporting Economic Development Activities and how these activities will benefit the residents of nearby Affordable Housing; and (iv) its strategy for engaging low-income stakeholders to inform its business strategy. An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it: (i) Demonstrates how the expected outcomes will address community needs; (ii) demonstrates a clear and compelling strategy for producing housing units targeted to Low-Income Families (for homeownership) and Very-Low Income Families (for rental); (iii) for Economic Development Activities, it demonstrates how its proposed Economic Development Activities fit within a Concerted Strategy and will benefit the residents of the surrounding Affordable Housing; and (iv) demonstrates that feedback from Low-Income stakeholders will inform the Applicant's business strategy.

(c) Organizational Capacity (25 points): In the Organizational Capacity section, the Applicant will discuss: (i) Its management team and key staff; (ii) the roles and responsibilities of those staff in managing a CMF Award; (iii) its past experience managing other Federal Awards; and (iv) its financial health and lending portfolio (if applicable).

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it demonstrates: (i) Strong qualifications of its key personnel with respect to their skills and experience identifying investments, underwriting similar projects, managing a portfolio of similar activities and ensuring compliance with program requirements; (ii) success in administering prior CMF Awards and/or other Federal program awards; (iii) strong financial health; and (iv) solid portfolio performance (if applicable).

(d) Scoring anomaly: If, in the case of a particular Application, the reviewers' total external Application review scores vary significantly, the CDFI Fund may, in its sole discretion, obtain the evaluation and numeric scoring of an additional reviewer to determine whether the anomalous score should be replaced with the score of the additional reviewer.

3. Internal Application Review: At the conclusion of the External Application Review phase, Applications will be ranked based on their external review score. Up to 50 of the highest scoring Applications in the External Application Review phase will be forwarded to Internal Application Review in descending order of rank score to receive further consideration for an Award. These forwarded applications will constitute the highly qualified pool. During the Internal Application Review, CDFI Fund staff will prioritize the Applications in the highly qualified pool for award based on the following criteria: (i) Final external Application review score, (ii) alignment with CMF statutory and policy priorities, and (iii) the overall quality of the Applicant's strategy.

In assessing the Application's alignment with CMF statutory and policy priorities, CDFI Fund staff will consider the following factors, including, but not limited to: The Applicant's proposed outcomes and benefits in areas of economic distress; income targeting of the portfolio of affordable units to be produced; and the amount of third-party private capital that the Applicant will attract to its Service Area.

In assessing the quality of the Applicant's strategy, the CDFI Fund staff will consider the following factors, including, but not limited to: (i) The quality of the Applicant's strategy with respect to how the strategy and financing activities address community needs; (ii) whether these outcomes are likely to be achieved if the Applicant's strategy is implemented and the extent to which these outcomes are quantifiable and evidence-based; (iii) whether the Applicant's projections are supported by its track record; (iv) whether the proposed financing activities will help to fill the financing gaps in their market; (v) whether the CMF funds will contribute to the Applicant offering more favorable rates and terms than are currently available in that market; (vi) the likely success of the strategy to leverage private capital; (vii) whether the strategy is adaptable to changing market conditions; (viii) whether the proposed deployment/redeployment schedule is realistic and achievable; and (ix) whether the Applicant has the appropriate financial, organizational, and programmatic capacity to implement the strategy.

The Internal Review will also include an analysis of the Applicant's likely capacity to: Meet award management standards; file appropriate reports and address findings from audits; and the Applicant's ability to effectively implement Federal requirements. Applicants may be re-prioritized for an award or award amounts may be reduced as a result of this analysis. In the case of an Applicant that has received awards from other Federal programs, the CDFI Fund reserves the right to contact officials from the appropriate Federal agency or agencies to determine whether the Recipient is in compliance with current or prior assistance agreements, and to take such information into consideration before making a CMF Award. In the case of an Applicant that has previously received funding through any CDFI Fund program, the CDFI Fund will consider and may, in its discretion, deduct up to 5 points from the External Application Review score for those Applicants (or their Affiliates) that, within 24 months prior to the Application deadline, are late in meeting reporting requirements for existing awards.

4. Selection: Once Applications have been internally evaluated and preliminary award determinations have been made, the Applications will be forwarded to a selecting official for a final award determination. After preliminary award determinations are made, the selecting official will review the list of potential Recipients to determine whether the Recipient pool meets the following statutory objectives:

(a) The potential Recipients' proposed Service Areas collectively represent broad geographic coverage throughout the United States; and

(b) The potential Recipients' proposed activities equitably represent both Metropolitan Areas and Non-Metropolitan Areas, as defined in the CMF Interim Rule, and as further set forth in the Application.

To the extent practicable, the CDFI Fund reserves the right to modify CMF Award amounts and/or the CMF Recipient pool if deemed necessary to achieve either of these desired outcomes. In order to evaluate the geographic coverage of the potential CMF Recipient pool, Applicants will be asked to designate one of the following three Service Area types in their Applications: Local, Statewide, or Multi-State. These Service Area types are further defined in the Application; the largest Service Area an Applicant can propose is a 10 state Multi-State Service Area. To achieve greater investment in Non-Metropolitan Areas and/or broader geographic coverage, the CDFI Fund may consider an Application ranked outside of the highly qualified pool to receive an award. However, the CDFI Fund will not award an Application that scores in the bottom 50 percent of the External Review score rankings.

In cases where the selecting official's award determination varies significantly from the initial CMF Award amount recommended by the CDFI Fund staff

review, the CMF Award recommendation will be forwarded to a reviewing official for final determination. The CDFI Fund, in its sole discretion, reserves the right to reject an Application and/or adjust CMF Award amounts as appropriate based on information obtained during the review process.

(c) Insured Depository Institution Applicants: In the case of Applicants that are Insured Depository Institutions or Insured Credit Unions, the CDFI Fund will consider safety and soundness information from the Appropriate Federal Banking Agency or Appropriate State Agency, as applicable. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal Banking Agency and Appropriate State Agency about both the CDFI Depository Institution Holding Company and the CDFI Insured Depository Institution that will expend and carry out the award. If the Appropriate Federal Banking Agency or Appropriate State Agency identifies safety and soundness concerns, the CDFI Fund will assess whether the concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

5. Right of Rejection: The CDFI Fund reserves the right to reject an Application if information (including administrative errors) comes to the attention of the CDFI Fund that adversely affects an Applicant's eligibility for an award, adversely affects the CDFI Fund's evaluation or scoring of an Application, or indicates fraud or mismanagement on the Applicant's part. If the CDFI Fund determines that any portion of the Application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If said changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information regarding the changes through the CDFI Fund's Web site. There is no right to appeal the CDFI Fund's award decisions. The CDFI Fund's award decisions are final.

6. Anticipated Award Announcement: The CDFI Fund anticipates making CMF Award announcements in late 2017 or early 2018.

VI. Federal Award Administration Information

A. *Award Notification:* Each successful Applicant will receive an email notification from the CDFI Fund stating that its Application has been approved for an award. Each Applicant not selected for an award will receive an email stating that a debriefing document has been provided in its AMIS account.

B. *Administrative and National Policy Requirements:* The CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the award or take other actions as it deems appropriate if, prior to entering into an Assistance Agreement, information (including an administrative error) comes to the CDFI Fund's attention that adversely affects the following: The Recipient's eligibility for an award; the CDFI Fund's evaluation of the Application; the Recipient's compliance with any requirement listed in the Uniform Requirements; or indicates fraud or mismanagement on the Recipient's part.

If the Recipient's certification status as a CDFI changes, the CDFI Fund reserves the right, in its sole discretion, to re-calculate the CMF Award, or modify the Assistance Agreement based on the Recipient's non-CDFI status.

By executing an Assistance Agreement, the Recipient agrees that, if the CDFI Fund becomes aware of any information (including an administrative error) prior to the Effective Date of the Assistance Agreement that either adversely affects the Recipient's eligibility for an CMF Award, or adversely affects the CDFI Fund's evaluation of the award Recipient's Application, or indicates fraud or mismanagement on the part of the Recipient, the CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the Assistance Agreement or take other actions as it deems appropriate.

The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient fails to return the Assistance Agreement, signed by an Authorized Representative of the award Recipient, and/or provide the CDFI Fund with any other requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA for any criteria described in Table 7:

TABLE 7—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements.	If a Recipient is a prior CDFI Fund award Recipient or Allocatee under any CDFI Fund program and is not current on the reporting requirements set forth in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee, as of the date of the Notice of Award, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, until said prior Recipient or Allocatee is current on the reporting requirements in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee. Please note that automated systems employed by the CDFI Fund for receipt of reports submitted electronically typically acknowledge only a report's receipt; such acknowledgment does not warrant that the report received was complete, nor that it met reporting requirements. If said prior Recipient or Allocatee is unable to meet this requirement within the timeframe set by the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Notice of Award and the CMF Award made under this NOFA.
Failure to maintain CDFI Certification (if applicable) or eligible Nonprofit Organization status (if applicable).	A Recipient must be a Certified CDFI or an eligible Nonprofit Organization, as each is defined in the CMF Interim Rule and this NOFA, prior to entering into an Assistance Agreement as well as during the application process. If, at any time prior to entering into an Assistance Agreement under this NOFA, an Applicant that is a Certified CDFI has submitted reports (or failed to submit an annual certification report as instructed by the CDFI Fund) to the CDFI Fund that demonstrate noncompliance with the requirements for certification, but the CDFI Fund has yet to make a final determination regarding whether or not the entity is Certified, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance. If the Applicant is unable to meet this requirement, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Notice of Award and the CMF Award made under this NOFA.

TABLE 7—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT—Continued

Requirement	Criteria
Pending resolution of non-compliance.	If, at any time prior to entering into an Assistance Agreement under this NOFA, an Applicant that is a prior CDFI Fund award Recipient or Allocatee under any CDFI Fund program has submitted reports to the CDFI Fund that demonstrate noncompliance with a previous assistance, award, or allocation agreement, but the CDFI Fund has yet to make a final determination regarding whether or not the entity is in default of its previous assistance, award, allocation, bond loan agreement, or agreement to guarantee, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance. If said prior Recipient or Allocatee is unable to meet this requirement, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Notice of Award and the CMF Award made under this NOFA.
Default or Noncompliance status.	If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that a Recipient is in default of a previously executed agreement with the CDFI Fund and the Recipient has been provided written notification of such determination, the CDFI Fund can delay entering into an Assistance Agreement, until the Recipient has cured the default, if applicable, by taking actions the CDFI Fund has specified within the specified timeframe. Further, if, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that a Recipient is noncompliant with an FY 2015 agreement, or with agreements for fiscal years thereafter, under any CDFI Fund program, the CDFI Fund can delay entering into an Assistance Agreement, until the Recipient has cured the noncompliance by taking actions the CDFI Fund has specified within the specified timeframe. If the Recipient is unable to meet the cure requirement, if applicable, within the specified timeframe, the CDFI Fund may terminate and rescind the Assistance Agreement and the CMF Award made under this NOFA.
Final Default and Sanctions	If the CDFI Fund has found the Recipient in final default of a prior executed agreement and provided notification of sanctions, the CDFI Fund may delay entering into an Assistance Agreement with the Recipient, impose conditions prior to entering in Assistance Agreement, or modify or rescind the CMF Award made under this NOFA within the time period specified in such notification.
Compliance with Federal civil rights requirements.	The CDFI Fund will terminate and rescind the Assistance Agreement and the CMF Award made under this NOFA if, prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last 3 years, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the CMF Award Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107); Title VIII of the Civil Rights Act of 1968, as amended (42 U.S.C. 3601 et seq.); and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Do Not Pay	The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the award Recipient is identified as ineligible to be a Recipient on the Do Not Pay database.
Safety and soundness	If it is determined that the Recipient is or will be incapable of meeting its CMF Award obligations, the CDFI Fund will deem the Recipient to be ineligible or require it to improve safety and soundness conditions prior to entering into an Assistance Agreement.

C. *Assistance Agreement:* Each Applicant that is selected to receive an award under this NOFA must enter into an Assistance Agreement with the CDFI Fund in order to become a Recipient and receive Payment. Each CMF Award under this NOFA generally will have a period of performance that begins with the announcement date of the award and continues until the end of the period of affordability, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement.

1. The Assistance Agreement will set forth certain required terms and conditions of the CMF Award, which will include, but not be limited to:

(a) The amount of the award;

(b) The approved uses of the award;

(c) The approved Service Area in which the award may be used;

(d) Performance goals and measures; and

(e) Reporting requirements for all Recipients.

2. The Assistance Agreement shall provide that, prior to any determination by the CDFI Fund that a Recipient has failed to comply substantially with the Act, the CMF Interim Rule, or the environmental quality regulations, the CDFI Fund shall provide the Recipient with reasonable notice and opportunity for hearing. For failure by the Recipient to comply substantially with the Assistance Agreement, the CDFI Fund may:

(a) Require changes in the performance goals set forth in the Assistance Agreement;

(b) Reduce or terminate the CMF Award; or

(c) Require repayment of any CMF Award that has been distributed to the Recipient.

3. The Assistance Agreement shall also provide that, if the CDFI Fund determines noncompliance with the terms and conditions of the Assistance Agreement on the part of the Recipient, the CDFI Fund may:

(a) Bar the Recipient from reapplying for any assistance from the CDFI Fund; or

(b) Take such other actions as the CDFI Fund deems appropriate or as set forth in the Assistance Agreement.

4. In addition to entering into an Assistance Agreement, each Applicant selected to receive a CMF Award must furnish to the CDFI Fund a certificate of good standing from the jurisdiction in which it was formed. The CDFI Fund may, in its sole discretion, also require the Applicant to furnish an opinion from its legal counsel, the content of which may be further specified in the Assistance Agreement, and which, among other matters, opines that:

(a) The Recipient is duly formed and in good standing in the jurisdiction in which it was formed and the jurisdiction(s) in which it transacts business;

(b) The Recipient has the authority to enter into the Assistance Agreement and

undertake the activities that are specified therein;

(c) The Recipient has no pending or threatened litigation that would materially affect its ability to enter into and carry out the activities specified in the Assistance Agreement;

(d) The Recipient is not in default of its articles of incorporation or formation, bylaws or operating agreements, other organizational or establishing documents, or any agreements with the Federal government; and

(e) The CMF affordability restrictions that are to be imposed by deed restrictions, covenants running with the land, or other CDFI Fund approved mechanisms are recordable and enforceable under the laws of the State and locality where the Recipient will undertake its CMF activities.

D. *Paperwork Reduction Act:* Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the CMF Program Application has been assigned the following control number: 1559–0036.

E. *Reporting:* The CDFI Fund will require each Recipient that receives a CMF Award through this NOFA to account for and report to the CDFI Fund on the use of the CMF Award. This will require Recipients to establish administrative controls, subject to the Uniform Administrative Requirements and other applicable OMB guidance. The CDFI Fund will collect information from each such Recipient on its use of the CMF Award at least once following Payment and more often if deemed appropriate by the CDFI Fund in its sole discretion. The CDFI Fund will provide guidance to Recipients outlining the format and content of the information required to be provided to describe how the funds were used.

The CDFI Fund may collect information from each Recipient including, but not limited to, an Annual Report with the components listed in Table 8:

TABLE 8—REPORTING REQUIREMENTS

Criteria	Description
Single Audit Narrative Report (or like report)	The Recipient must submit, via AMIS, a Single Audit Narrative Report for each year of its period of performance notifying the CDFI Fund whether it is required to have a single audit pursuant to OMB Single Audit requirements.
Single Audit (if applicable) (or similar report)	A Recipient that is a non-profit entity that expends $750,000 or more in Federal Awards during its fiscal year must have a single audit conducted for that year. If a Recipient is required to complete a Single Audit Report, it should be submitted to the Federal Audit Clearinghouse. See 2 CFR part 200, subpart F-Audit Requirements in the Uniform Federal Award Requirements. For-profit award Recipients will be required to complete and submit a similar report directly to the CDFI Fund.
Performance Report	The Recipient must submit a performance report not less than annually, which is a progress report on the Recipient's use of the CMF Award towards meeting its Performance Goals, affordable housing outcomes, and the Recipient's overall performance. The CMF performance report covers the Announcement Date through the Investment Period for the CMF Award and the ten-year Affordability Period for each project. The Investment Period shall mean the period beginning with the effective date of the Assistance Agreement and ending not earlier than the fifth year anniversary of the effective date or as otherwise established in the Assistance Agreement. The Affordability Period shall mean, for each CMF-funded project, the period beginning on the date when the project is placed into service and consisting of the full ten consecutive years thereafter or as otherwise established in the Assistance Agreement.
Explanation of Noncompliance (as applicable) or successor report.	If the award Recipient fails to meet a performance goal or reporting requirements, it must submit the Explanation of Noncompliance via AMIS.

Each Recipient is responsible for the timely and complete submission of the annual reporting documents. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements set forth in the Assistance Agreement and to assess the impact of the CMF. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

F. *Financial Management and Accounting:* The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the CMF Award. These systems must be sufficient to permit the preparation of reports required by general and program specific terms and conditions, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used in accordance with the Federal statutes, regulations, and the terms and conditions of the CMF Award.

The cost principles used by Recipients must be consistent with Federal cost principles; must support the accumulation of costs as required by the principles; and must provide for adequate documentation to support costs charged to the CMF Award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes and regulations, the Assistance Agreement, and related guidance; evaluate and monitor compliance; take action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. *Availability:* The CDFI Fund will respond to questions and provide support concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. ET, starting on the date of the publication of this NOFA until the close of business on the third day preceding the Application deadline. The CDFI Fund will not respond to questions or provide support concerning the Application that are received after 5:00 p.m. ET on said date, until after the Application deadline. CDFI Fund IT support will be available until 5:00 p.m.

ET on date of the Application deadline. Applications and other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's Web site at *http://www.cdfifund.gov/cmf.* The CDFI Fund will post on its Web site responses to questions of general applicability regarding the CMF.

B. *The CDFI Fund's contact information is listed in Table 9:*

TABLE 9—CONTACT INFORMATION

Type of question	Telephone number (not toll free)	Email addresses/AMIS Service Request
CMF	202–653–0421	Submit an AMIS Service Request in AMIS or *cmf@cdfi.treas.gov.*
CDFI Certification	202–653–0421	Submit an AMIS Service Request in AMIS.
Compliance Monitoring and Evaluation	202–653–0421	Submit an AMIS Service Request in AMIS.
Information Technology Support	202–653–0422	Submit an AMIS Service Request or email *AMIS@cdfi.treas.gov.*

The preferred method of contact is to submit a Service Request (SR) within AMIS. For a CMF Application question, select ''General Inquiry'' for the record type and select ''CMF-Application'' for the type. For a CDFI Certification or Compliance question, select ''General Inquiry'' for the record type and select the appropriate type. For Information Technology, select ''General Inquiry'' for the record type and select ''CMF–AMIS technical problem'' for the type. Failure to select the appropriate type of SR could result in delays in responding to your question.

C. *Communication with the CDFI Fund:* The CDFI Fund will use AMIS to communicate with Applicants and Recipients, using the contact information maintained in their respective AMIS accounts. Therefore, the Recipient and any Subsidiaries, signatories, and Affiliates must maintain accurate contact information (including contact persons and Authorized Representatives, email addresses, fax numbers, phone numbers, and office addresses) in its AMIS account(s). For more information about AMIS please see the Help documents posted at *https://amis.cdfifund.gov/s/Training.*

Authority: Pub. L. 110–289. 12 U.S.C. 4701, 12 CFR part 1805, 12 CFR part 1807, 12 CFR part 1815, 12 U.S.C. 4502.

Mary Ann Donovan,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2017–13722 Filed 6–29–17; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Orders

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons whose property and interests in property are blocked pursuant to the following authorities: Executive Order (E.O.) 13660, E.O. 13661, and E.O. 13685, or who are subject to the prohibitions of one or more directives under E.O. 13662.

DATES: OFAC's actions described in this notice were effective on June 20, 2017.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's Web site at *http://www.treasury.gov/ofac.* A complete listing of persons determined to be subject to one or more directives under E.O. 13662, as discussed in detail in this Notice, can be found in the Sectoral Sanctions Identifications List at *http://Start Printed Page 95304www.treasury.gov/resource-center/sanctions/SDN-List/Pages/ssi_list.aspx.*

Notice of OFAC Actions

On June 20, 2017, OFAC blocked the property and interests in property of the following persons pursuant to E.O. 13660, ''Blocking Property of Certain Persons Contributing to the Situation in Ukraine'':

1. MURATOV, Aleksey (a.k.a. MURATOV, Aleksey Valentinovich (Cyrillic: МУРАТОВ, Алексей Валентинович); a.k.a. MURATOV, Alexei), Moscow, Russia; Donetsk, Ukraine; DOB 17 Feb 1978; Gender Male (individual) [UKRAINE–EO13660].
2. BULGAKOV, Vadim Viktorovich, Crimea, Ukraine; DOB 30 Jan 1969; POB Simferopol, Crimea, Ukraine; Gender Male (individual) [UKRAINE–EO13660].
3. KHORSHEVA, Natalya Ivanovna (a.k.a. KHORSHEVA, Nataliya; a.k.a. KHORSHEVA, Natalya), Luhansk, Ukraine; DOB 14 Jul 1972; Gender Female (individual) [UKRAINE–EO13660].
4. JAROSH, Petr Grigorievich (a.k.a. YAROSH, Petro; a.k.a. YAROSH, Pyotr), Crimea, Ukraine; DOB 30 Jan 1971; POB Skvortsovo village, Simferopol region, Crimea, Ukraine; Gender Male (individual) [UKRAINE–EO13660].
5. KOSTRUBITSKY, Aleksey Aleksandrovich (a.k.a. KOSTRUBITSKIJ, Aleksej Aleksandrovich; a.k.a. KOSTRUBITSKY, Alexei; a.k.a. KOSTRUBITSKY, Olexiy Oleksandrovych; a.k.a. KOSTRUBYTSKYY, Oleksiy), in/h A–0050, Donetsk, Ukraine; DOB 24 Aug 1978; POB Russia; Gender Male (individual) [UKRAINE–EO13660].
6. DIKIY, Aleksey Aleksandrovich (a.k.a. DIKIJ, Aleksej Aleksandrovich; a.k.a. DIKIY, Olexiy Oleksandrovych; a.k.a. DYKYY, Oleksiy), Donetsk, Ukraine; DOB 05 Jul 1974; Gender Male (individual) [UKRAINE–EO13660].
7. NIKITINA, Irina (a.k.a. NIKITINA, Irina Petrovna; a.k.a. NIKITINA, Iryna Petrivna), Ukraine; DOB 17 May 1968; Gender Female (individual) [UKRAINE–EO13660].
8. KAMSHILOV, Oleg Anatolievich, Crimea, Ukraine; DOB 1969; POB Piketnoy Marjanovsky District, Omsk Region, Russia; nationality Russia; Gender Male (individual) [UKRAINE–EO13660].

9. KORNET, Igor Aleksandrovich (a.k.a. KORNET, Igor; a.k.a. KORNET, Ihor), Luhansk, Ukraine; DOB 29 Apr 1973; Gender Male (individual) [UKRAINE–EO13660].
10. MELNIKOV, Andrei (a.k.a. MELNIKOV, Andrey; a.k.a. MELNIKOV, Andrey Gennadevich; a.k.a. MELNIKOVA, Andreya Gennadevicha), 13 pr., Simferopol, Crimea, Ukraine; DOB 03 Sep 1969; Email Address *me@rk.gov.ru;* Gender Male (individual) [UKRAINE–EO13660].
11. PASECHNIK, Leonid Ivanovich (a.k.a. PASECHNYK, Leonid; a.k.a. PASICHNYK, Leonid), Ukraine; DOB 15 Mar 1970; Gender Male (individual) [UKRAINE–EO13660].
12. NIKULOV, Gennadii Anatolievich (a.k.a. NIKULOV, Gennady A.), Russia; DOB 17 Feb 1967; nationality Russia (individual) [UKRAINE–EO13660].
13. RYAUZOV, Denis Yuryevich (a.k.a. JURJEVICH, Ryauzov Denis; a.k.a. RJAUZOW, Denis; a.k.a. RYAUZOV, Denis; a.k.a. RYAUZOW, Denis), Russia; DOB 23 May 1974; POB Omsk, Siberia, Russia; nationality Russia (individual) [UKRAINE–EO13660].
14. UTKIN, Dmitriy Valeryevich, Russia; DOB 1970; POB Ukraine; Gender Male (individual) [UKRAINE–EO13660] (Linked To: PRIVATE MILITARY COMPANY 'WAGNER').
15. NAZAROV, Sergey Makarovich, Russia; DOB 27 Jul 1961; POB Kizel, Russia; Gender Male; Deputy Minister of Economic Development of the Russian Federation (individual) [UKRAINE–EO13660] [UKRAINE–EO13661].
16. CENTRAL REPUBLIC BANK (a.k.a. CENTRAL NATIONAL BANK OF THE DONETSK PEOPLE'S REPUBLIC), Prospekt Mira 8a, Donetsk 83015, Ukraine; Web site *www.crb-dnr.ru;* Email Address *bank@crb-dnr.ru* [UKRAINE–EO13660].
17. STATE BANK LUHANSK PEOPLE'S REPUBLIC, Str. T. G. Shevchenko, d. 1, Luhansk 91000, Ukraine; Web site *www.gosbank.su;* Email Address *bank@gosbank.su* [UKRAINE–EO13660].
18. TSMRBANK, OOO (a.k.a. BANK 'CENTER FOR INTERNATIONAL SETTLEMENTS' LLC; a.k.a. BANK 'TSENTR MEZHDUNARODNYKH RASCHETOV' OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU; a.k.a. LLC TSMRBANK), ul. Palikha, d. 10, Str. 7, Moscow 127055, Russia; Web site *www.nko-cmr.ru;* Email Address *cmr@cmrbank.ru;* BIK (RU) 044525059; Registration ID 1157700005759 (Russia); Tax ID No. 7750056670 (Russia); Government Gazette Number 45000256 (Russia) [UKRAINE–EO13660].
19. BIKE CENTER (a.k.a. BAIK. V. TSENTR; a.k.a. BAIK. V. TSENTR, OOO; a.k.a. BIKE V. CENTER), Nizhnije Mnevniki, 110, Moscow, Russia; ul. Nikitskaya B. D.11/4, korp. 3, Moscow 103009, Russia; 1 ¼, str.3 ul. Nikitskaya B., Moscow 103009, Russia; Trade License No. 1037739620390 (Russia); Government Gazette Number 54842899 (Russia) [UKRAINE–EO13660].
20. 'WOLF' HOLDING OF SECURITY STRUCTURES (a.k.a. DEFENSE HOLDING STRUCTURE 'WOLF'; a.k.a. HOLDING SECURITY STRUCTURE WOLF; a.k.a. KHOLDING OKHRANNYKH STRUKTUR VOLK; a.k.a. WOLF HOLDING COMPANY), ul. Panferova d. 18, Moscow 119261, Russia; Nizhniye Mnevniki, 110, Moscow, Russia; Tax ID No. 7736640919 (Russia) [UKRAINE–EO13660].
21. PRIVATE MILITARY COMPANY 'WAGNER' (a.k.a. CHASTNAYA VOENNAYA KOMPANIYA 'VAGNER'; a.k.a. CHVK VAGNER; a.k.a. PMC WAGNER), Russia [UKRAINE–EO13660].

On June 20, 2017, OFAC determined that AK Transneft OAO owns, directly or indirectly, a 50 percent or greater interest in the entities listed below. As a result of such ownership, these entities are subject to the prohibitions of Directive 2 (as amended) of September 12, 2014, issued pursuant to E.O. 13662, ''Blocking Property of Additional Persons Contributing to the Situation in Ukraine'' and 31 CFR 589.406 and 589.802, and following the Secretary of the Treasury's determination of July 16, 2014 pursuant to section l(a)(i) of E.O. 13662 with respect to the energy sector of the Russian Federation economy.

1. CHERNOMORTRANSNEFT, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'CHERNOMORSKIE MAGISTRALNYE NEFTEPROVODY'; a.k.a. JSC 'CHERNOMORTRANSNEFT'; a.k.a. OPEN JOINT–STOCK COMPANY 'BLACK SEA OIL TRUNK PIPELINES'), ul. Sheskharis, Novorossisk, Krasnodarski Kr. 353911, Russia; Web site *www.nvr.transneft.ru;* Email Address *fogela@nvr.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1022302384136 (Russia); Tax ID No. 2315072242 (Russia); Government Gazette Number 00139011 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
2. DSD, OOO (a.k.a. LIMITED LIABILITY COMPANY 'FAR EAST CONSTRUCTION DIRECTION'; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'DALNEVOSTOCHNAYA STROITELNAYA DIREKTSIYA'; a.k.a. ''LLC 'DSD' ''), 163 ul. Volochaevskaya, Khabarovsk, Khabarovski Kr. 680000, Russia; Web site *dsdvsto.ru;* Email Address *dsd-it@dsd.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1092724004581 (Russia); Government Gazette Number 60668690 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
3. GIPROTRUBOPROVOD, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'INSTITUT PO PROEKTIROVANIYU MAGISTRALNYKH TRUBOPROVODOV'; a.k.a. OJSC 'GIPROTRUBOPROVOD'; a.k.a. OPEN JOINT–STOCK COMPANY 'INSTITUTE ON PLANNING OF OIL TRUNK PIPELINES'), d. 24 korp. 1 ul. Vavilova, Moscow 119334, Russia; Web site *www.gtp.transneft.ru;* Email Address *agafontsevaa@gtp.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027700002660 (Russia); Tax ID No. 7710022410 (Russia); Government Gazette Number 00148406 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
4. NPF TRANSNEFT, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'NEGOSUDARSTVENNY PENSIONNY FOND 'TRANSNEFT'), d. 5⁄7 str. 2, 3 ul. Shchipok, Moscow 115054, Russia; Web site *npf-transneft.ru;* Email Address *mail@npf-transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1157700011017 (Russia); Tax ID No. 9705044356 (Russia); Government Gazette Number 54769346 (Russia); For more information on directives,

please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).

5. SVYAZTRANSNEFT, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'SVYAZ OBEKTOV TRANSPORTA I DOBYCHI NEFTI'; a.k.a. JSC 'SVYAZTRANSNEFT'; a.k.a. OPEN JOINT–STOCK COMPANY 'COMMUNICATION OF THE OBJECTS OF OIL TRANSPORTATION AND EXTRACTION'), 12 ul. Nametkina, Moscow 117420, Russia; Web site *www.oilnet.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027739420961 (Russia); Tax ID No. 7723011906 (Russia); Government Gazette Number 00140058 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
6. TRANSNEFT FINANS, OOO (a.k.a. LIMITED LIABILITY COMPANY 'TRANSNEFT FINANS'; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'TRANSNEFT FINANS'; a.k.a. TRANSNEFT FINANCE LIMITED), d. 24 korp. 1 ul. Vavilova, Moscow 119334, Russia; Web site *transneftfinance.ru;* Email Address *sobolevmi@tnf.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1067746400622 (Russia); Tax ID No. 7736536770 (Russia); Government Gazette Number 94473510 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
7. TRANSNEFT–DIASKAN, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT—DIASKAN'; a.k.a. JSC 'TRANSNEFT–DIASCAN'; a.k.a. JSC CTD 'DIASKAN'; a.k.a. OPEN JOINT–STOCK COMPANY 'CENTRE OF TECHNICAL DIAGNOSTICS'), 7 ul. Kuibysheva, Lukhovitsy, Raion Moskovskaya Obl. 140501, Russia; Web site *www.diascan.ru;* Email Address *korotkovaa@ctd.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1025007389527 (Russia); Tax ID No. 5072703668 (Russia); Government Gazette Number 18024722 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
8. TRANSNEFT–DRUZHBA, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT—DRUZHBA'; a.k.a. JSC 'DRUZHBA'; a.k.a. OPEN JOINT–STOCK COMPANY ''OIL TRUNK PIPELINES 'DRUZHBA' ''), d. 113 ul. Uralskaya, Bryansk, Bryanskaya Obl. 241020, Russia; Web site *www.druzhbamn.ru;* Email Address *androsovaeg@brn.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1023202736754 (Russia); Tax ID No. 3235002178 (Russia); Government Gazette Number 10453441 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
9. TRANSNEFTEPRODUKT, PAO (f.k.a. AKTSIONERNOE OBSHCHESTVO AKTSIONERNAYA KOMPANIYA TRUBOPROVODNOGO TRANSPORTA NEFTEPRODUKTOV TRANSNEFTEPRODUKT; a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFTEPRODUKT'; a.k.a. JSC 'TRANSNEFTEPRODUKT'; a.k.a. OPEN JOINT–STOCK COMPANY 'TRANSNEFTEPRODUKT'; a.k.a. TRANSNEFTEPRODUCT JOINT–STOCK CO), 8A prospekt Vernadskogo, Moscow 119311, Russia; Email Address *nurymbetovage@ak.aktnp.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027700054140 (Russia); Tax ID No. 7709027196 (Russia); Government Gazette Number 00044474 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
10. TRANSNEFT–MEDIA, OOO (a.k.a. LIMITED LIABILITY COMPANY 'TRANSPRESS'; a.k.a. LLC 'TRANSPRESS'; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'TRANSNEFT–MEDIA'), d. 4 str.1 ul. Shchipok, Moscow 115093, Russia; Web site *http://en.media.transneft.ru/;* Email Address *transpress.ttn@gmail.com;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027700276218 (Russia); Tax ID No. 7734019544 (Russia); Government Gazette Number 36559384 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
11. TRANSNEFT–METROLOGIYA, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFTMETROLOGIYA'; a.k.a. CJSC 'CENTRE MO'; a.k.a. CLOSED JOINT–STOCK COMPANY 'CENTRE OF METROLOGICAL PROVISION'), d. 16 korp. 1 ul. Dobrolyubova, Moscow 127254, Russia; *Web site centermo.ru;* Email Address *chernyshovi@cmo.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1037739028491 (Russia); Tax ID No. 7723107453 (Russia); Government Gazette Number 42771562 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
12. TRANSNEFT–OKHRANA, OOO (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'TRANSNEFT–OKHRANA'), d. 12 str. 2 ul. Nametkina, Moscow 117420, Russia; Email Address *babaevii@tno.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1147746651898 (Russia); Tax ID No. 7728881149 (Russia); Government Gazette Number 16983393 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
13. TRANSNEFT–PODVODSERVIS, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT–PODVODSERVIS'; a.k.a. JSC 'VOLZHSKY PODVODNIK'; a.k.a. OPEN JOINT–STOCK COMPANY 'VOLZHSKY PODVODNIK'), 19A ul. Larina, Nizhni Novgorod, Nizhegorodskaya Obl. 603152, Russia; Email Address *alexandrovan@*

vp.transneft.ru; Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1025201982520 (Russia); Tax ID No. 5250000820 (Russia); Government Gazette Number 04884421 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).

14. TRANSNEFT–PRIKAME, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT—PRIKAME'; a.k.a. JSC 'SZMN'; a.k.a. OPEN JOINT–STOCK COMPANY 'NORTH–WESTERN OIL TRUNK PIPELINES'; a.k.a. TRANSNEFT–PRIKAMYE AO), 26A ul. Nikolaya Ershova, Kazan, Tatarstan Resp. 420061, Russia; Web site *www.szmn.ru;* Email Address *hanovat@kaz.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1021601763820 (Russia); Tax ID No. 1645000340 (Russia); Government Gazette Number 00139264 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
15. TRANSNEFT–PRIVOLGA, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT–PRIVOLGA'; a.k.a. JSC PRIVOLZHSKNEFTEPROVOD; a.k.a. OPEN JOINT–STOCK COMPANY 'PRIVOLZHSK OIL TRUNK PIPELINES'), 100 ul. Leninskaya, Samara, Samarskaya Obl. 443020, Russia; Web site *pmn.ru;* Email Address *ootorg@pmn.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1026301416371 (Russia); Tax ID No. 6317024749 (Russia); Government Gazette Number 00139117 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
16. TRANSNEFT–SEVER, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT—SEVER'; a.k.a. OPEN JOINT–STOCK COMPANY 'NORTH OIL TRUNK PIPELINES'; a.k.a. ''JSC 'SMN'''), 2/1 prospekt A.I.Zeryunova, Ukhta, Komi Resp. 169313, Russia; Web site *www.severnyemn.ru;* Email Address *post@uht.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1021100730353 (Russia); Tax ID No. 1102016594 (Russia); Government Gazette Number 00139672 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
17. TRANSNEFT–SIBIR, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT–SIBIR'; a.k.a. JSC SIBNEFTEPROVOD; a.k.a. OPEN JOINT–STOCK COMPANY 'SIBNEFTEPROVOD'; a.k.a. TRANSNEFT SIBIRIA, JSC), 139 ul. Respubliki, Tyumen, Tyumenskaya Obl. 625048, Russia; Web site *http://sibnefteprovod.transneft.ru;* Email Address *beschastnyhav@ueso.tmn.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027200789220 (Russia); Tax ID No. 7201000726 (Russia); Government Gazette Number 00139229 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
18. TRANSNEFT–TSENTRALNAYA SIBIR, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT—TSENTRALNAYA SIBIR'; a.k.a. JSC 'TSENTRSIBNEFTEPROVOD'; a.k.a. OPEN JOINT–STOCK COMPANY 'OIL TRUNK PIPELINES OF CENTRAL SIBERIA'), 24 ul. Naberezhnaya Reki Ushaiki, Tomsk, Tomskaya Obl. 634050, Russia; Web site *csib.tomsk.ru;* Email Address *bagamanovmn@tom.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1027000867101 (Russia); Tax ID No. 7017004366 (Russia); Government Gazette Number 00139181 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
19. TRANSNEFT–URAL, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO 'TRANSNEFT–URAL'; a.k.a. JSC 'URALSIBNEFTEPROVOD'; a.k.a. OPEN JOINT–STOCK COMPANY 'CHERNYAEV URAL–SIBERIAN OIL TRUNK PIPELINES'), 10 ul. Krupskoi, Ufa, Bashkortostan Resp. 450077, Russia; Web site *www.usmn.ru;* Email Address *nekrasovaov@ufa.transneft.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1020203226230 (Russia); Tax ID No. 0278039018 (Russia); Government Gazette Number 00139608 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).
20. TSUP VSTO, OOO (a.k.a. LIMITED LIABILITY COMPANY 'CENTRE OF MANAGEMENT OF THE PROJECT EASTERN SIBERIA–PACIFIC OCEAN'; a.k.a. LLC TSUP VSTO; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'TSENTR UPRAVLENIYA PROEKTOM 'VOSTOCHNAYA SIBIR—TIKHI OKEAN'), 2–B ul. Gorkogo, Angarsk, Irkutskaya Obl. 665830, Russia; Web site *cupvsto.ru;* Executive Order 13662 Directive Determination—Subject to Directive 2; Registration ID 1053801124519 (Russia); Tax ID No. 3801079270 (Russia); Government Gazette Number 77642401 (Russia); For more information on directives, please visit the following link: *http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: AK TRANSNEFT OAO).

On June 20, 2017, OFAC blocked the property and interests in property of the following persons pursuant to E.O. 13685, ''Blocking Property of Certain Persons and Prohibiting Certain Transactions With Respect to the Crimea Region of Ukraine'':

1. IS BANK, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO KOMMERCHESKI BANK INDUSTRIALNY SBEREGATELNY BANK; f.k.a. CLOSED JOINT STOCK COMPANY COMMERCIAL BANK 'INDUSTRIAL SAVINGS BANK'; a.k.a. JOINT–STOCK COMPANY COMMERCIAL BANK 'INDUSTRIAL SAVINGS BANK'; a.k.a. JSC CB 'IS BANK'), Eldoradovsky per 7, Moscow 125167, Russia; 29/UL, prospect Kirova, Simferopol, Crimea 295011, Ukraine; Building 160, Office 104, Kievskaya Street, Simferopol, Crimea 295493, Ukraine; Building 25, Lenin Street, Kerch, Crimea 298300, Ukraine; alt. SWIFT/BIC RISB RU MM; BIK (RU) 044525349;

Registration ID 1027739339715 (Russia); Tax ID No. 7744001673 (Russia); Government Gazette Number 40199908 (Russia) [UKRAINE–EO13685].

2. JOINT STOCK COMMERCIAL BANK RUBLEV (a.k.a. AKTSIONERNOE OBSHCHESTVO KOMMERCHESKI BANK RUBLEV; a.k.a. BANK RUBLEV; a.k.a. JSC CB 'RUBLEV'; a.k.a. RUBLEV BANK), Elokhovsky passage, Building 3, p. 2, Metro—Baumanskaya, Moscow 105066, Russia; 12 Sevastopol Street, Simferopol, Crimea, Ukraine; 6 Gogol Street, Sevastopol, Crimea, Ukraine; alt. SWIFT/BIC COUE RU MM; BIK (RU) 044525253; Registration ID 1027700159233 (Russia); Tax ID No. 7744001151 (Russia); Government Gazette Number 40100094 (Russia) [UKRAINE–EO13685].
3. JOINT STOCK COMPANY BLACK SEA BANK OF DEVELOPMENT AND RECONSTRUCTION (a.k.a. AKTSIONERNOE OBSHCHESTVO CHERNOMORSKI BANK RAZVITIYA I REKONSTRUKTSII; a.k.a. BANK CHBRR, AO; f.k.a. BANK CHBRR, PAO; a.k.a. 'CHERNOMORSKI BANK RAZVITIYA I REKONSTRUKTSII, OTKRYTOE AKTSIONERNOE OBSHCHESTVO'; a.k.a. JSC 'BLACK SEA BANK FOR DEVELOPMENT & RECONSTRUCTION'; f.k.a. OPEN JOINT STOCK COMPANY BLACK SEA DEVELOPMENT AND RECONSTRUCTION BANK), 24 ul. Bolshevistskaya, Simferopol, Crimea 295001, Ukraine; BIK (RU) 043510101; Registration ID 1149102030186 (Russia); Tax ID No. 9102019769 (Russia); Government Gazette Number 00204814 (Russia); License 3527 (Russia) [UKRAINE–EO13685].
4. JOINT-STOCK COMPANY COMMERCIAL BANK NORTH CREDIT (a.k.a. JSC CB NORTH CREDIT; a.k.a. NORTH CREDIT BANK), Building 27, Herzen Street, Vologda, Vologda Oblast 160000, Russia; Building 29a, Zhelyabova Street, Simferopol, Crimea 295011, Ukraine; ul. Gertsena 27, Vologda, Vologodskaya Oblast 160000, Russia; alt. SWIFT/BIC NOCR RU 21; BIK (RU) 041909769; Registration ID 1022900001772 (Russia); Tax ID No. 2901009852 (Russia) [UKRAINE–EO13685].
5. TAATTA, AO (a.k.a. BANK TAATTA; a.k.a. BANK TAATTA AKTSIONERNOE OBSHCHESTVO; a.k.a. JOINT STOCK COMPANY TAATTA BANK; a.k.a. JSC TAATTA BANK), 36 ul. Chepalova, Yakutsk, Sakha (Yakutiya) Resp. 677018, Russia; Bld. 41, Bolshaya Morskaya Street, Sevastopol, Crimea 299011, Ukraine; Bld. 66, Kirova Avenue, Simferopol, Crimea, Ukraine; Bld. 36, Kulakova Street, Sevastopol, Crimea, Ukraine; alt. SWIFT/BIC TAAARU8Y; BIK (RU) 049805709; Registration ID 1021400000380 (Russia); Tax ID No. 1435126628 (Russia); Government Gazette Number 09287233 (Russia); License 1249 (Russia) [UKRAINE–EO13685].
6. VVB, PAO (f.k.a. COMMERCIAL JOINT-STOCK INCORPORATION BANK YAROSLAVICH; f.k.a. KOMMERCHESKI BANK YAROSLAVICH, PAO; a.k.a. PJSC BANK VVB; a.k.a. PUBLIC JOINT-STOCK COMPANY BANK VVB; a.k.a. PUBLICHNOE AKTSIONERNOE OBSHCHESTVO BANK VVB; a.k.a. PUBLICHNOYE JOINT-STOCK COMPANY BANK VVB), 3A ul., 4-ya Bastionnaya, Sevastopol, Crimea 299011, Ukraine; Voronina, 10, Sevastopol, Crimea 299011, Ukraine; 39A Ul. Suvorova, Sevastopol, Crimea, Ukraine; 5 Per. Pionerskiy, Simferopol, Crimea, Ukraine; alt. SWIFT/BIC YARO RU 21; BIK (RU) 046711106; alt. BIK (RU) 043510133 [UKRAINE–EO13685].
7. OBORONLOGISTIKA, OOO (a.k.a. OBORONLOGISTICS LIMITED LIABILITY COMPANY; a.k.a. OBORONLOGISTICS LLC; a.k.a. OBORONLOGISTIKA LLC; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'OBORONLOGISTIKA'), d. 18 str. 3 prospekt Komsomolski, Moscow 119021, Russia; ul. Goncharnaya, house 28, building 2, Moscow 115172, Russia; Web site *Oboronlogistika.ru;* Email Address *v.boyko@oboronservice.ru;* alt. Email Address *Info@oboronlogistika.ru;* Registration ID 1117746641572 (Russia); Tax ID No. 7718857267 (Russia); Government Gazette Number 30167631 (Russia) [UKRAINE–EO13685].
8. KPSK, OOO (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU 'KRYMSKAYA PERVAYA STRAKHOVAYA KOMPANIYA'; a.k.a. OOO 'KRYMSKAYA PERVAYA STRAKHOVAYA KOMPANIYA'), 29 ul. Karla Marksa, Simferopol, Crimea 295006, Ukraine; Web site *kpsk-ins.ru;* Email Address *kpsk-ins@yandex.ru;* Registration ID 1149102007933 (Russia); Tax ID No. 9102006047 (Russia); Government Gazette Number 00132598 (Russia) [UKRAINE–EO13685].
9. IFDK, ZAO (a.k.a. CLOSED JOINT STOCK COMPANY 'IFD KAPITAL'; a.k.a. IFD KAPITAL; a.k.a. IFD KAPITAL GROUP; a.k.a. IFD–CAPITAL; a.k.a. IFD–KAPITAL; a.k.a. ZAKRYTOE AKTSIONERNOE OBSHCHESTVO 'IFD KAPITAL'; f.k.a. ZAKRYTOE AKTSIONERNOE OBSHCHESTVO IFD KARITAL), 6 naberezhnaya, Krasnopresnenskaya, Moscow 123100, Russia; Web site *www.ifdk.com;* Email Address *info@ifdk.com;* Registration ID 1027703007452 (Russia); Tax ID No. 7703354743 (Russia); Government Gazette Number 59109241 (Russia) [UKRAINE–EO13685].
10. RIVIERA SUNRISE RESORT & SPA (a.k.a. RIVIERA SUNRISE RESORT AND SPA), Lenin St. 2, Alushta, Crimea 29850, Ukraine; Email Address *info.alushta@rivierasunrise.com* [UKRAINE–EO13685].
11. PLAKSINA, Olga (a.k.a. PLAKSINA, Olga Vladimirovna), Russia; DOB 03 Mar 1974; POB Moscow, Russia; Gender Female (individual) [UKRAINE–EO13685].

Dated: June 23 2017.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2017–13673 Filed 6–29–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple IRS Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection request(s) 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 the collection(s) listed below.

DATES: Comments should be received on or before July 31, 2017 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 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Employer's Annual Tax Return for Agricultural Employees.

OMB Control Number: 1545–0035.

Type of Review: Revision of a currently approved collection.

Abstract: Sections 3101(a) and (b), and 3111(a) and (b), 3402(p), and 6011(a) and (b) of the Internal Revenue Code and sections 31.6011(a)–1 and 31.6011(a)–4 of the Employment Tax Regulations require agricultural employers to report (a) the employees' and employers' FICA taxes on wages and (b) the amounts withheld for income tax. Form 943 is used for this purpose. Sections 3101(a) and (b), 3111(a) and (b), and 6011(a) and (b) of the Internal Revenue Code and section 31.6011(a)–1 of the Employment Tax Regulations require agricultural employers in Puerto Rico to report the employees' and employers' FICA taxes on wages. Form 943–PR is used for this purpose. Section 6302(c) of the Internal Revenue Code and section 31.6302–l(g) of the Employment Tax Regulations require agricultural employers who are semiweekly depositors to deposit the taxes accumulated during the semiweekly period within 3 banking days of the end of the period. Section 31.6302–l(c)(3) of the Employment Tax Regulations requires that agricultural employers, who on any day within a deposit period accumulate $100,000 or more of employment taxes, must deposit them by the close of the next banking day. Forms 943–A and 943A–PR are optional forms that may be used by agricultural employers to show their tax liabilities for the semiweekly periods and $100,000 one-day rule. Form 943–X is used to correct errors made on Form 943, Employer's Annual Federal Tax Return for Agricultural Employees, for one year only. Form 943–X–PR, for use in Puerto Rico, is used to correct errors made on Form 943, Employer's Annual Federal Tax Return for Agricultural Employees, for one year only. (Use este formulario para corregir errores hechos en el Formulario 943–PR, Planilla para la Declaración Anual de la Contribución Federal del Patrono de Empleados Agrícolas, para un solo año.) Form 943 Sch R allows (1) an agent appointed by an employer or payer or (2) a customer who enters into a contract that meets the requirements under 7705(e)(2) or (3) a client who enters into a service agreement described under Regulations section 31.3504–2(b)(2) with a Certified Professional Employer Organization, to allocate information reported on Form 943 to each client.

Form: 943,943–PR, 943–A, 943A–PR, 943–X, 943X–PR, 943–R.

Affected Public: Businesses or other for-profits, Farms.

Estimated Total Annual Burden Hours: 10,883,138.

Title: Form 1023—Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code and Form 1023–EZ, Streamlined.

OMB Control Number: 1545–0056.

Type of Review: Revision of a currently approved collection.

Abstract: Form 1023 is filed by applicants seeking Federal income tax exemption as organization described in section 501(c)(3). IRS uses the information to determine if the applicant is exempt and whether the applicant is a private foundation. Form 1023–EZ is a simplified version of Form 1023, to be filed by organizations who meet certain criteria.

Form: 1023, 1023–EZ.

Affected Public: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 4,714,236.

Title: Foreign Tax Credit (Individual, Estate, or Trust).

OMB Control Number: 1545–0121.

Type of Review: Extension without change of a currently approved collection.

Abstract: Form 1116 is used by individuals (including nonresident aliens) estates or trusts that paid foreign income taxes on U.S. taxable income to compute the foreign tax credit. This information is used by the IRS to verify the foreign tax credit.

Form: 116.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 25,066,693.

Title: Application for Approval of Prototype Simplified Employee Pension (SEP) or Savings Incentive Match Plan for Employees of Small Employers (SIMPLE IRA Plan).

OMB Control Number: 1545–0199.

Type of Review: Extension without change of a currently approved collection.

Abstract: This form is used by banks, credit unions, insurance companies, and trade or professional associations to apply for approval of a Simplified Employee Pension Plan or Savings Incentive Match Plan to be used by more than one employer. The data collected is used to determine if the prototype plan submitted is an approved plan.

Form: 5306A.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 407.

Title: Safe-harbor lease information returns.

OMB Control Number: 1545–0923.

Type of Review: Extension without change of a currently approved collection.

Abstract: These regulations provide guidance to persons executing lease agreements involving tax-exempt entities under section 168(h) of the Internal Revenue Code. The regulations are necessary to implement congressionally enacted legislation and elections for certain previously tax-exempt organizations and certain tax-exempt controlled entities.

Form: None.

Affected Public: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 3,000.

Title: Estimated Income Tax for Estates and Trusts.

OMB Control Number: 1545–0971.

Type of Review: Extension without change of a currently approved collection.

Abstract: Internal Revenue Code section 6654(1) imposes a penalty on trusts, and in certain circumstances, a decedent's estate, for underpayment of estimated tax. Form 1041–ES is used by the fiduciary to make the estimated tax payments. For first-time filers, the form is available in an Over The Counter (OTC) version at IRS offices. For previous filers, the form is sent to them by the IRS with preprinted vouchers in the Optical Character Resolution (OCR) version.

Form: 1041–ES.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 3,161,236.

Title: Form 1099–S—Proceeds From Real Estate Transactions.

OMB Control Number: 1545–0997.

Type of Review: Revision of a currently approved collection.

Abstract: Form 1099–S is used by the real estate reporting person to report proceeds from a real estate transaction to the IRS.

Form: 1099–S.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 411,744.

Title: Form 8655-Reporting Agent Authorization; Revenue Procedure 2012–32.

OMB Control Number: 1545–1058.

Type of Review: Extension without change of a currently approved collection.

Abstract: Form 8655: Allows a taxpayer to designate a reporting agent to file certain employment tax returns electronically, and to submit Federal tax deposits. This form allows IRS to disclose tax account information and to provide duplicate copies of taxpayer correspondence to authorized agents. Reporting agents are persons or organizations preparing and filing electronically the federal tax returns and/or submitting federal tax deposits. Revenue Procedure 2012–32. This revenue procedure provides the requirements for completing and submitting Form 8655, Reporting Agent Authorization (Authorization). An Authorization allows a taxpayer to designate a Reporting Agent to perform the following acts on behalf of a taxpayer.

Form: 8655.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 819,050.

Title: Enhanced Oil Recovery Credit.

OMB Control Number: 1545–1292.

Type of Review: Revision of a currently approved collection.

Abstract: This regulation provides guidance concerning the costs subject to the enhanced oil recovery credit, the circumstances under which the credit is available, and procedures for certifying to the Internal Revenue Service that a project meets the requirements of section 43(c) of the Internal Revenue Code.

Form: 8830.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 12,527.

Title: CO–88–90 (TD 8530) Limitation on Net Operating Loss Carryforwards and Certain Built-in Losses Following Ownership Change; Special Rule for Value of a Loss Corporation Under the Jurisdiction.

OMB Control Number: 1545–1324.

Type of Review: Revision of a currently approved collection.

Abstract: This information serves as evidence of an election to apply section 382(1)(6) in lieu of section 382(1)(5) and an election to apply the provisions of the regulations. It is required by the Internal Revenue Service to assure that the proper amount of carryover attributes are used by a loss corporation following specified types of ownership changes.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 63.

Title: TD 8566 (Final)—General Asset Accounts Under the Accelerated Cost Recovery System.

OMB Control Number: 1545–1331.

Type of Review: Extension without change of a currently approved collection.

Abstract: The regulations describe the time and manner of making the election described in IRC Section 168(i)(4). Basic information regarding this election is necessary to monitor compliance with the rules in the IRC Section 168.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 250.

Title: Cognitive and Psychological Research.

OMB Control Number: 1545–1349.

Type of Review: Revision of a currently approved collection.

Abstract: The proposed research will improve the quality of the data collection by examining the psychological and cognitive aspects of methods and procedures such as: interviewing processes, forms redesign, survey and tax collection technology and operating procedures (internal and external in nature).

Form: None.

Affected Public: Individuals and Businesses, other for-profit organizations.

Estimated Total Annual Burden Hours: 18,000.

Title: Form 8866-Interest Computation Under the Look-Back Method for Property Depreciated Under the Income Forecast Method.

OMB Control Number: 1545–1622.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Small Business Job Protection Act of 1996 requires taxpayers whom claim depreciation deductions on property placed in service after September 13, 1995, under the income forecast method to pay (allow taxpayers to receive) interest based on the recalculation of depreciation. Form 8866 must be used in order to compute and report interest due or to be refunded under IRC 167 (g)(2). The IRS uses Form 8866 to determine if the interest has been figured correctly.

Form: 8866.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 45,738.

Title: Extraterritorial Income Exclusion Elections.

OMB Control Number: 1545–1731.

Type of Review: Extension without change of a currently approved collection.

Abstract: A taxpayer that wants to revoke its election to be treated as a domestic corporation for all purposes of the Internal Revenue Code (Code) must file a revocation statement with the Internal Revenue Service (IRS). This revenue procedure provides guidance for implementing the elections (and revocation of such elections) established under the ''FSC Repeal and Extraterritorial Income Exclusion Act of 2000.''

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 19.

Title: Summary of Archer MSAs.

OMB Control Number: 1545–1743.

Type of Review: Extension without change of a currently approved collection.

Abstract: This form is used by the IRS to determine whether numerical limits set forth in section 220(j)(1) have been exceeded.

Form: 8851.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,540,000.

Title: Revenue Procedure 2004–29—Statistical Sampling in Sec. 274 Context.

OMB Control Number: 1545–1847.

Type of Review: Extension without change of a currently approved collection.

Abstract: For taxpayers desiring to establish for purposes of Sec. 274(n) (2), (A), (C), (D), or (E) that a portion of the total amount of substantiated expenses incurred for meals and entertainment is excepted from the 50% limitation of Sec. 274(n), the revenue procedure requires that taxpayers maintain adequate documentation to support the statistical application, sample unit findings, and all aspects of the sample plan.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 3,200.

Title: Revenue Procedure 2010–52, Extension of the Amortization Period for Plan Sponsor of a Multiemployer Pension Plan.

OMB Control Number: 1545–1890.

Type of Review: Extension without change of a currently approved collection.

Abstract: This revenue procedure describes the process for obtaining an extension of the amortization period for the minimum funding standards set forth in section 412(e) of the Code.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,500.

Title: Form 13560, Health Plan Administrator (HPA) Return of Funds.

OMB Control Number: 1545–1891.

Type of Review: Extension without change of a currently approved collection.

Abstract: Form 13560 is completed by Health Plan Administrators (HPAs) and accompanies a return of funds in order to ensure proper handling. This form serves as supporting documentation for any funds returned by an HPA and clarifies where the payment should be applied and why it is being sent.

Form: 13560.

Affected Public: State, Local, and Tribal Government.

Estimated Total Annual Burden Hours: 50.

Title: Rollover of Gain from Qualified Small Business Stock to Another Qualified Small Business Stock.

OMB Control Number: 1545–1893.

Type of Review: Extension without change of a currently approved collection.

Abstract: These regulations relating to the application of section 1045 of the Internal Revenue Code (Code) to partnerships and their partners and provide rules regarding the deferral of gain on a partnership's sale of qualified small business stock (QSB stock) and a partner's sale of QSB stock distributed by a partnership. These regulations also provide rules for a taxpayer (other than a C corporation) who sells QSB stock and purchases replacement QSB stock through a partnership.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,500.

Title: (TD 9212) Final, Source of Compensation for Labor or Personal Services.

OMB Control Number: 1545–1900.

Type of Review: Extension without change of a currently approved collection.

Abstract: The regulation describes the appropriate bases for determining the source of income from labor or personal services performed partly within and partly without the United States. The information required in Sec. 1.861–4(b)(2)(ii)(D) and (D)(6) will enable an employee to source certain fringe benefits on a geographical basis. The collections of information will allow the IRS to verify these determinations.

Form: None.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 10,000.

Title: TD 9210—LIFO Recapture Under Section 1363(d).

OMB Control Number: 1545–1906.

Type of Review: Extension without change of a currently approved collection.

Abstract: This collection of information is required to inform the IRS of partnerships electing to increase the basis of inventory to reflect any amount included in a partner's income under section 1363(d). Section 1.1363–2(e)(ii) allows a partnership to elect to adjust the basis of its inventory to take account of LIFO recapture. Section 1.1363–2(e)(3) provides guidance on how to make this election.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 200.

Title: Form 14134, Application for Certificate of Subordination of Federal Tax Lien.

OMB Control Number: 1545–2174.

Type of Review: Extension without change of a currently approved collection.

Abstract: The collection of information is required by 26 CFR 301.6325–1(b)(5) for consideration of the United States discharging property from the federal tax lien and is required by 26 CFR 301.6325–1(d)(4) for consideration that the United States subordinate its interest in property. These forms will provide guidance to ensure proper documentation is submitted to the Agency.

Form: 14134, 14135.

Affected Public: Businesses or other for-profits, Farms, Not-for-profit institutions.

Estimated Total Annual Burden Hours: 22,665.

Title: Affordable Care Act Notice Relating to Rescissions.

OMB Control Number: 1545–2180.

Type of Review: Revision of a currently approved collection.

Abstract: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, and patient protections.

Form: None.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Total Annual Burden Hours: 20.

Title: REG–118315–12 (FINAL), Health Insurance Providers Fee and Form 8963, Report of Health Insurance Provider Information.

OMB Control Number: 1545–2249.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Affordable Care Act imposes an annual fee on health insurance providers that provide health insurance for United States health risks (a covered entity). IRS final regulations, which implements the Affordable Care Act, describe how the IRS will administer the health insurance providers fee. This information collection covered under this request are the recordkeeping requirements prescribed in § 57.2(e)(2) that each member of a controlled group are to maintain records of consent to the controlled group's selection of the designated entity. Reporting requirements under § 57.3 will be reported through Form 8963, ''Report of Health Insurance Provider Information''. File Form 8963, Report of Health Insurance Provider Information, to report net premiums written for health insurance of United States health risks. The information reported will be used by the IRS to calculate the annual fee on health insurance providers.

Form: 8963.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 18,208.

Title: Notice 2017–9—De Minimis Error Safe Harbor to the I.R.C. §§ 6721 and 6722 Penalties.

OMB Control Number: 1545–2270.

Type of Review: Extension without change of a currently approved collection.

Abstract: Under 6722(c)(3)(B) payees may elect that an exception to penalties not apply so that penalties may apply if payors don't provide corrected returns and statements. The collection of information will be this election, a retraction of the election, or specified

retention of records of elections or retractions. The collection is necessary for the effective operation of the exception and election framework. Respondents are payees or payors.

Form: None.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 760,569.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 23, 2017.

Jennifer P. Leonard,

Treasury PRA Clearance Officer.

[FR Doc. 2017–13593 Filed 6–29–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Bureau of the Fiscal Service Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection request(s) 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 the collection(s) listed below.

DATES: Comments should be received on or before July 31, 2017 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 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Bureau of the Fiscal Service (FS)

Title: Legacy Treasury Direct Forms.

OMB Control Number: 1530–0042.

Type of Review: Revision of a currently approved collection.

Abstract: Used to purchase and maintain Treasury Bills, Notes and Bonds.

Form: FS Form 5236, FS Form 5178, FS Form 5235, FS Form 5188, FS Form 5191, FS Form 5179.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 4,528.

Title: Resolution For Transactions Involving Treasury Securities.

OMB Control Number: 1530–0049.

Type of Review: Extension without change of a currently approved collection.

Abstract: Completed by an official of an organization that is designated to act on behalf of the organization.

Form: FS Form 1010.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 430.

Title: Direct Deposit Sign-Up Form.

OMB Control Number: 1530–0050.

Type of Review: Extension without change of a currently approved collection.

Abstract: Used to request the direct deposit of Series HH or Series H bond interest payments or a savings bond redemption payment.

Form: FS Form 5396.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 9,167.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 23, 2017.

Jennifer P. Leonard,

Treasury PRA Clearance Officer.

[FR Doc. 2017–13592 Filed 6–29–17; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Signing Authority for Corporate and LLC Officials

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection request(s) 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 the collection(s) listed below.

DATES: Comments should be received on or before July 31, 2017 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 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

Title: Signing Authority for Corporate and LLC Officials.

OMB Control Number: 1513–0036.

Type of Review: Revision of a currently approved collection.

Abstract: Under the IRC at 26 U.S.C. 6061, any return, statement, or other document required to be made under the internal revenue laws or regulations ''shall be signed in accordance with forms or regulations'' prescribed by the Secretary of the Treasury. Issued under that section's authority, but not specifically required by the TTB regulations, corporations and limited liability companies (LLCs) use TTB F 5100.1 or its electronic equivalent to identify specific corporate or LLC officials or employees, by name or by position title, authorized by the entity's articles of incorporation, bylaws, or governing officials to act on behalf of, or sign documents for, the entity in TTB matters. This information collection is necessary to ensure that only duly authorized individuals sign documents submitted to TTB on behalf of corporations or LLCs.

Form: TTB F 5100.1 N/A, TTB F 5100.1.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,056.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 23, 2017.

Jennifer P. Leonard,

Treasury PRA Clearance Officer.

[FR Doc. 2017–13594 Filed 6–29–17; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C., App. 2, that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet on August 1–2, 2017, at 999 California Street, San Francisco, CA, from 9:00 a.m. until 5:00 p.m. (Pacific) on August 1 and from 8:45 a.m. to 12:45 p.m. (Pacific) on August 2. All sessions will be open to the public, and for interested parties who cannot attend in person, there is a toll-free telephone number (800) 767–1750; access code 56978#.

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War in 1990–1991.

The Committee will review VA program activities related to Gulf War Veterans' illnesses, and updates on relevant scientific research published since the last Committee meeting. Presentations will include updates on the VA Gulf War research program, along with presentations describing new areas of research in sleep, aging, and neuroscience that can be applied to the health problems of Gulf War Veterans. Also, there will be a discussion of Committee business and activities.

The meeting will include time reserved for public comments in the afternoon. A sign-up sheet for 5-minute comments will be available at the meeting. Individuals who wish to address the Committee may submit a 1–2 page summary of their comments for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Dr. Victor Kalasinsky via email at *victor.kalasinsky@va.gov.* Any member of the public seeking additional information should contact Dr. Kalasinsky, Designated Federal Officer, at (202) 443–5600.

Dated: June 27, 2017.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2017–13774 Filed 6–29–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—NEW]

Agency Information Collection Activity: General Release for Medical Provider Information to the Department of Veterans Affairs (VA) and Authorization and Consent To Release Information to the Department of Veterans Affairs

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 29, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900—NEW'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor at (202) 461–5870.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: General Release for Medical Provider Information to the Department of Veterans Affairs (VA) (VA Form 21–4142) and Authorization and Consent to Release Information to the Department of Veterans Affairs (VA Form 21–4142a).

OMB Control Number: 2900—NEW.

Type of Review: New collection.

Abstract: VA Forms 21–4142 will be used to authorize the disclosure of information to the VA and 21–4142a will be used to gather the necessary information to request medical provider information to the VA.

Affected Public: Individuals and households.

Estimated Annual Burden: 11,033 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 132,400.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–13731 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0708]

Agency Information Collection Activity Under OMB Review: Evidence for Transfer Entitlement of Education Benefits (CFR 21.7080)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of

1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 31, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–00708'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Department Clearance Officer—OI&T (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *Cynthia.harvey.pryor@va.gov.* Please refer to ''OMB Control No. 2900–0708'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3020, 38 U.S.C. 3319; 44 U.S.C. 3501–3521.

Title: Evidence for Transfer Entitlement of Education Benefits (CFR 21.7080).

OMB Control Number: 2900–0708.

Type of Review: Revision of a currently approved collection.

Abstract: Servicemembers on active duty may request to designate up to a maximum of 18 months of their educational entitlement to their spouse, one or more of their children, or a combination of the spouse and children. VA will accept DOD Form 2366–1 as evidence that the servicemember must submit it in writing to VA, the name of each dependent, the number of months of entitlement transferred to each dependent, and the period (beginning date or ending date) for which the transfer will be effective for each designated dependent. VA will use the information shown on DOD Form 2366–1 to determine whether the dependent qualifies to receive education benefits under the transfer of entitlement provision of law.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 69 on April 12, 2017, page 17742.

Affected Public: Individuals or households.

Estimated Annual Burden: 11,311 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 135,735.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–13729 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0521]

Agency Information Collection Activity Under OMB Review: Credit Underwriting Standards and Procedures for Processing VA Guaranteed Loans

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 31, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0521'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0521.''

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–21.

Title: Credit Underwriting Standards and Procedures for Processing VA Guaranteed Loans (VA Form 26–1820, VA Form 26–8497, VA Form 26–8497a).

OMB Control Number: 2900–0521.

Type of Review: Extension of an approved collection.

Abstract: Lenders must obtain specific information concerning a veteran's credit history in order to properly underwrite the veteran's loan. VA loans may not be guaranteed unless the veteran is a satisfactory credit risk. The data collected on the following forms are used to ensure that applications for VA-guaranteed loans are underwritten in a reasonable and prudent manner.

a. VA Form 26–1820 is completed by lenders closing VA-guaranteed and insured loans under the automatic or prior approval procedures.

b. VA Form 26–8497 is used by lenders to verify a loan applicant's income and employment information when making guaranteed and insured loans. VA does not require the exclusive use of this form for verification purposes, any alternative verification document would be acceptable provided that all information requested on VA Form 26–8497 is provided.

c. Lenders making guaranteed and insured loans complete VA Form 26–8497a to verify the applicant's deposits in banks and other savings institutions.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 82, No. 64, Wednesday, April 5, 2017, pages 16664 and 16665.

Affected Public: Individuals or households.

Estimated Annual Burden:

VA Form 26–1820 150,000 hours
VA From 26–8497 25,000 hours
VA Form 26–8497a 12,500 hours

Estimated Average Burden per Respondent:

VA Form 26–1820 15 minutes
VA Form 26–8497 10 minutes
VA Form 26–8497a 5 minutes

Frequency of Response: One time.

Estimated Number of Respondents:

VA Form 26–1820 600,000
VA Form 26–8497 150,000
VA Form 26–8497a 150,000

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Enterprise Records Service, Office of Quality and Compliance, Department of Veterans Affairs.

[FR Doc. 2017–13728 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0816]

Agency Information Collection Activity under OMB Review: Board of Veterans' Appeals Voice of the Veteran Appellant Satisfaction Survey

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Board of Veterans' Appeals, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 31, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0816'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0816'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Board of Veterans' Appeals Voice of the Veteran Appellant Satisfaction Survey.

OMB Control Number: 2900–0816.

Type of Review: Extension of a Currently Approved Collection.

Abstract: This notice solicits comments information needed to enable the Board to gauge the effectiveness of the Board's process delivering information and assistance to Veterans and other appellants, as well as assess Veterans' and other appellants' overall level of satisfaction with the Board's appeals process. In addition, the data will be used by the Board to make improvements to the Board's operational processes and service delivery, which in turn, will enable the Board to serve Veterans in the most efficient and effective way possible.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 82, No. 78, Tuesday, April 25, 2017, page 19140.

Affected Public: Individuals and households.

Estimated Annual Burden: 1,571 hours.

Estimated Average Burden per Respondent: 5 minutes for telephone survey; 12 minutes for eSurvey.

Frequency of Response: One-time.

Estimated Number of Respondents: 14,727 (11,782 for telephone survey; 2,945 for eSurvey).

By direction of the Secretary.

Cynthia Harvey-Pryor,

Agency Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–13730 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0546]

Agency Information Collection Activity Under OMB Review: Gravesite Reservation Questionnaire

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the National Cemetery Administration (NCA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 31, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0546 in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0546.''

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–3521.

Title: Gravesite Reservation Questionnaire (2-year).

OMB Control Number: 2900–0546.

Type of Review: Revision of a currently approved collection.

Abstract: The information is needed to determine if individuals holding gravesite set-asides wish to retain their set-aside or their wish to relinquish it. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 82, No. 74, Wednesday, April 19, 2017, page 18540.

Affected Public: Individual or House Holds.

Estimated Annual Burden: 4,166 hours.

Estimated Average Burden per Respondent: 10 minutes each.

Frequency of Response: One-time.

Estimated Number of Respondents: 25,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Enterprise Records Service, Office of Quality and Compliance, Department of Veterans Affairs.

[FR Doc. 2017–13732 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0116]

Agency Information Collection Activity Under OMB Review: Notice to Department of Veterans Affairs of Veteran or Beneficiary Incarcerated in Penal Institution

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 31, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0116'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0116'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Notice to Department of Veterans Affairs of Veteran or Beneficiary Incarcerated in Penal Institution (VA Form 21–4193).

OMB Control Number: 2900–0116.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21–4193 is used to gather information from penal institutions about incarcerated VA beneficiaries. When beneficiaries are incarcerated in penal institutions in excess of 60 days after conviction, VA benefits are reduced or terminated. Without this collection of information, VA would be unable to accurately adjust the rates of incarcerated beneficiaries and overpayments would result.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 69 on April 12, 2017, pages 17742 and 17743.

Affected Public: Individuals or Households.

Estimated Annual Burden: 416.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 1,664.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–13727 Filed 6–29–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414

Medicare Program; CY 2018 Updates to the Quality Payment Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–5522–P]

RIN 0938–AT13

Medicare Program; CY 2018 Updates to the Quality Payment Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program for eligible clinicians. Under the Quality Payment Program, eligible clinicians can participate via one of two tracks: Advanced Alternative Payment Models (APMs); or the Merit-based Incentive Payment System (MIPS). We began implementing the Quality Payment Program through rulemaking for calendar year (CY) 2017. This rule provides proposed updates for the second and future years of the Quality Payment Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 21, 2017.

ADDRESSES: In commenting, please refer to file code CMS–5522–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four 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–5522–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5522–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Molly MacHarris, (410) 786–4461, for inquiries related to MIPS.

Benjamin Chin, (410) 786–0679, for inquiries related to APMs.

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ABC™ Achievable Benchmark of Care
ACO Accountable Care Organization
API Application Programming Interface
APM Alternative Payment Model
APRN Advanced Practice Registered Nurse
ASC Ambulatory Surgical Center
ASPE HHS' Office of the Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CAH Critical Access Hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CBSA Core Based Statistical Area
CEHRT Certified EHR technology
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CJR Comprehensive Care for Joint Replacement
COI Collection of Information
CPR Customary, Prevailing, and Reasonable
CPS Composite Performance Score
CPT Current Procedural Terminology
CQM Clinical Quality Measure
CY Calendar Year
eCQM Electronic Clinician Quality Measure
ED Emergency Department
EHR Electronic Health Record
EP Eligible Professional
ESRD End-Stage Renal Disease
FFS Fee-for-Service
FR Federal Register
FQHC Federally Qualified Health Center
GAO Government Accountability Office
HIE Health Information Exchange
HIPAA Health Insurance Portability and Accountability Act of 1996
HITECH Health Information Technology for Economic and Clinical Health
HPSA Health Professional Shortage Area
HHS Department of Health & Human Services
HRSA Health Resources and Services Administration
IHS Indian Health Service
IT Information Technology
LDO Large Dialysis Organization
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MEI Medicare Economic Index
MIPAA Medicare Improvements for Patients and Providers Act of 2008
MIPS Merit-based Incentive Payment System
MLR Minimum Loss Rate
MSPB Medicare Spending per Beneficiary
MSR Minimum Savings Rate
MUA Medically Underserved Area
NPI National Provider Identifier
OCM Oncology Care Model
ONC Office of the National Coordinator for Health Information Technology
PECOS Medicare Provider Enrollment, Chain, and Ownership System
PFPMs Physician-Focused Payment Models
PFS Physician Fee Schedule
PHI Protected Health Information
PHS Public Health Service
PQRS Physician Quality Reporting System
PTAC Physician-Focused Payment Model Technical Advisory Committee
QCDR Qualified Clinical Data Registry
QP Qualifying APM Participant
QRDA Quality Reporting Document Architecture
QRUR Quality and Resource Use Reports
RBRVS Resource-Based Relative Value Scale

RFI Request for Information
RHC Rural Health Clinic
RIA Regulatory Impact Analysis
RVU Relative Value Unit
SGR Sustainable Growth Rate
TCPI Transforming Clinical Practice Initiative
TIN Tax Identification Number
VBP Value-Based Purchasing
VM Value-Based Payment Modifier
VPS Volume Performance Standard

I. Executive Summary and Background

A. Overview

This proposed rule would make payment and policy changes to the Quality Payment Program. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) amended title XVIII of the Social Security Act (the Act) to repeal the Medicare sustainable growth rate (SGR), to reauthorize the Children's Health Insurance Program, and to strengthen Medicare access by improving physician and other clinician payments and making other improvements.

The MACRA advances a forward-looking, coordinated framework for clinicians to successfully take part in the Quality Payment Program that rewards value and outcomes in one of two ways:

- Advanced Alternative Payment Models (Advanced APMs).
- Merit-based Incentive Payment System (MIPS).

These policies are collectively referred to as the Quality Payment Program. Recognizing that the Quality Payment Program represents a major milestone in the way that we bring quality measurement and improvement together with payment, we have taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible. Our goal is to support patients and clinicians in making their own decisions about health care using data driven insights, increasingly aligned and meaningful quality measures, and technology that allows clinicians to focus on providing high quality healthcare for their patients. We believe our existing APMs alongside the proposals in this proposed rule provide opportunities that support state flexibility, local leadership, regulatory relief and innovative approaches to improve quality accessibility and affordability. By driving changes in how care is delivered, we believe the Quality Payment Program supports eligible clinicians in improving the health of their patients and increasing care efficiency. To implement this vision, the Quality Payment Program emphasizes high-value care and patient outcomes while minimizing burden on eligible clinicians; the Program is also designed to be flexible, transparent, and structured to improve over time with input from clinicians, patients, and other stakeholders. We have sought and continue to seek feedback from the health care community through various public avenues such as rulemaking, listening sessions and stakeholder engagement. Last year, when we engaged in rulemaking to establish policies for effective implementation of the Quality Payment Program, we did so with the explicit understanding that technology, infrastructure, physician support systems, and clinical practices will change over the next few years. For more information, see the Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period (81 FR 77008, November 4, 2016), hereinafter referred to as the ''CY 2017 Quality Payment Program final rule.'' In addition, we are aware of the diversity among clinician practices in their experience with quality-based payments. As a result of these factors, we expect the Quality Payment Program to evolve over multiple years in order to achieve our national goals. To date, we have laid the groundwork for expansion toward an innovative, outcome-focused, patient-centered, resource-effective health system that leverages health information technology to support clinicians and patients and builds collaboration across care settings. This proposed rule is the next part of a staged approach to develop policies that are reflective of system capabilities and grounded in our core strategies to drive progress and reform efforts. We commit to continue evolving these policies.

CMS strives to put patients first, ensuring that they can make decisions about their own healthcare along with their clinicians. We want to ensure innovative approaches to improve quality, accessibility and affordability while paying particular attention to improving clinicians and beneficiaries experience when interacting with CMS programs. The Quality Payment Program aims to (1) support care improvement by focusing on better outcomes for patients, decreased clinician burden, and preservation of independent clinical practice; (2) promote adoption of APMs that align incentives for high-quality, low-cost care across healthcare stakeholders; and (3) advance existing delivery system reform efforts, including ensuring a smooth transition to a healthcare system that promotes high-value, efficient care through unification of CMS legacy programs.

We previously finalized the transition year Quality Payment Program policies in the CY 2017 Quality Payment Program final rule. In that final rule, we implemented policies to improve physician and other clinician payments by changing the way Medicare incorporates quality measurement into payments and by developing new policies to address and incentivize participation in APMs. The final rule established the Quality Payment Program and its two interrelated pathways: Advanced APMs, and the MIPS. The final rule established incentives for participation in Advanced APMs, supporting the goals of transitioning from fee-for-service (FFS) payments to payments for quality and value, including approaches that focus on better care, smarter spending, and healthier people. The final rule included definitions and processes to identify Qualifying APM Participants (QPs) in Advanced APMs and outlined the criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations to the Secretary on proposals for physician-focused payment models (PFPMs).

The final rule also established policies to implement MIPS, a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals (EPs). As prescribed by MACRA, MIPS focuses on the following: quality—including a set of evidence-based, specialty-specific standards; cost; practice-based improvement activities; and use of certified electronic health record (EHR) technology (CEHRT) to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies.

In this proposed rule, we are building and improving Quality Payment Program policies that will be familiar to stakeholders and are designed to integrate easily across clinical practices during the second and future years of implementation. We strive to continue our focus on priorities that can drive improvements toward better patient outcomes without creating undue

burden for clinicians. In this proposed rule, we also address elements of MACRA that were not included in the first year of the program, including virtual groups, facility-based measurement, and improvement scoring. We also include proposals to continue implementing elements of MACRA that do not take effect in the first or second year of the Quality Payment Program, including policies related to the All-Payer Combination Option for identifying QPs and assessing eligible clinicians' participation in Other Payer Advanced APMs. To provide unity and consistency across the two paths of the Quality Payment Program, MIPS and APMs, in this proposed rule we have referred to the second year of the program as ''Quality Payment Program Year 2.''

B. Quality Payment Program Strategic Objectives

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77010), after extensive outreach with clinicians, patients and other stakeholders, we created six strategic objectives to drive continued progress and improvement. These objectives guided our final policies and will guide our future rulemaking in order to design, implement, and evolve a Quality Payment Program that aims to improve health outcomes, promote efficiency, minimize burden of participation, and provide fairness and transparency in operations. These strategic objectives are as follows: (1) To improve beneficiary outcomes and engage patients through patient-centered Advanced APM and MIPS policies; (2) to enhance clinician experience through flexible and transparent program design and interactions with easy-to-use program tools; (3) to increase the availability and adoption of Advanced APMs; (4) to promote program understanding and maximize participation through customized communication, education, outreach and support that meet the needs of the diversity of physician practices and patients, especially the unique needs of small practices; (5) to improve data and information sharing to provide accurate, timely, and actionable feedback to clinicians and other stakeholders; and (6) to promote IT systems capabilities that meet the needs of users and are seamless, efficient and valuable on the front and back-end. We also believe it is important to ensure the Quality Payment Program maintains operational excellence as the program develops. Therefore we are adding a seventh objective, specifically to ensure operational excellence in program implementation and ongoing development. More information on these objectives and the Quality Payment Program can be found at *www.qpp.cms.gov*.

With these objectives, we recognize that the Quality Payment Program provides new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families, and caregivers and to improve care coordination and population health management. In addition, we recognize that by developing a program that is flexible instead of one-size-fits-all, clinicians will be able to choose to participate in a way that is best for them, their practice, and their patients. For eligible clinicians interested in APMs, we believe that by setting ambitious yet achievable goals, eligible clinicians will move with greater certainty toward these new approaches of delivering care. APMs are a vital part of bending the Medicare cost curve by encouraging the delivery of high-quality, low-cost care. To these ends, and to allow this program to work for all stakeholders, we further recognize that we must provide ongoing education, support, and technical assistance so that clinicians can understand program requirements, use available tools to enhance their practices, and improve quality and progress toward participation in APMs if that is the best choice for their practice. Finally, we understand that we must achieve excellence in program management, focusing on customer needs, promoting problem-solving, teamwork, and leadership to provide continuous improvements in the Quality Payment Program.

C. One Quality Payment Program

Clinicians have told us that they do not separate their patient care into domains, and that the Quality Payment Program needs to reflect typical clinical workflows in order to achieve its goal of better patient care. Advanced APMs, the focus of one pathway of the Quality Payment Program, contribute to better care and smarter spending by allowing physicians and other clinicians to deliver coordinated, customized, high-value care to their patients in a streamlined and cost-effective manner. Within MIPS, the second pathway of the Quality Payment Program, we believe that integration into typical clinical workflows can best be accomplished by making connections across the four statutory pillars of the MIPS incentive structure—quality, clinical practice improvement activities (referred to as ''improvement activities''), meaningful use of CEHRT (referred to as ''advancing care information''), and resource use (referred to as ''cost'')—and by emphasizing that the Quality Payment Program is at its core about improving the quality of patient care.

Although there are two separate pathways within the Quality Payment Program, the Advanced APM and MIPS tracks both contribute toward the goal of seamless integration of the Quality Payment Program into clinical practice workflows. Advanced APMs promote this seamless integration by way of payment methodology and design that incentivize care coordination, and the MIPS builds the capacity of eligible clinicians across the four pillars of MIPS to prepare them for participation in MIPS APMs and Advanced APMs in later years of the Quality Payment Program. Indeed, the bedrock of the Quality Payment Program is high-value, patient-centered care, informed by useful feedback, in a continuous cycle of improvement. The principal way that MIPS measures quality of care is through a set of clinical quality measures (CQMs) from which MIPS eligible clinicians can select. The CQMs are evidence-based, and the vast majority are created or supported by clinicians. Over time, the portfolio of quality measures will grow and develop, driving towards outcomes that are of the greatest importance to patients and clinicians and away from process, or ''check the box'' type measures.

Through MIPS, we have the opportunity to measure quality, not only through evidence-based quality measures, but also by accounting for activities that clinicians themselves identify: namely, practice-driven quality improvement. MIPS also requires us to assess whether CEHRT is used meaningfully. Based on significant feedback, this area was simplified to support the exchange of patient information, engagement of patients in their own care through technology, and the way technology specifically supports the quality goals selected by the practice. The cost performance category was simplified and weighted at zero percent of the final score for the transition year of CY 2017 to allow clinicians an opportunity to ease into the Quality Payment Program. We further note the cost performance category requires no separate submissions for participation which minimizes burden on clinicians. The assessment of cost is a vital part of ensuring that clinicians are providing Medicare beneficiaries with high-value care. Given the primary focus on value, we indicated in the CY 2017 Quality

Payment Program final rule our intention to align cost measures with quality measures over time in the scoring system (81 FR 77010). That is, we established special policies for the first year of the Quality Payment Program, which enabled a ramp-up and gradual transition with less financial risk for clinicians in the transition year. We called this approach ''pick your pace'' and allowed clinicians and groups to participate in MIPS through flexible means while avoiding a negative payment adjustment. In this proposed rule, we continue the slow ramp-up of the Quality Payment Program by establishing special policies for Program Year 2 aimed at encouraging successful participation in the program while reducing burden, reducing the number of clinicians required to participate, and preparing clinicians for the CY 2019 performance period (CY 2021 payment year).

D. Summary of the Major Provisions

1. Quality Payment Program Year 2

We believe the second year of the Quality Payment Program should build upon the foundation that has been established which provides a trajectory for clinicians to value-based care. This trajectory provides to clinicians the ability to participate in the program through two pathways: MIPS and Advanced APMs. As we indicated in the CY 2017 Quality Payment Program final rule (81 FR 77011), we believed that a second transition period would be necessary to build upon the iterative learning and development period as we build towards a steady state. We continue to believe this to be true and have therefore crafted our policies to extend flexibilities into Quality Payment Program Year 2.

2. Small Practices

The support of small, independent practices remains an important thematic objective for the implementation of the Quality Payment Program and is expected to be carried throughout future rulemaking. For MIPS performance periods occurring in 2017, many small practices are excluded from new requirements due to the low-volume threshold, which was set at less than or equal to $30,000 in Medicare Part B allowed charges or less than or equal to 100 Medicare Part B patients. We have heard feedback, however, from many small practices that challenges still exist in their ability to participate in the program. We are proposing additional flexibilities including: Implementing the virtual groups provisions; increasing the low-volume threshold to less than or equal to $90,000 in Medicare Part B allowed charges or less than or equal to 200 Medicare Part B patients; adding a significant hardship exception from the advancing care information performance category for MIPS eligible clinicians in small practices; and providing bonus points that are added to the final scores of MIPS eligible clinicians who are in small practices. We believe that these additional flexibilities and reduction in barriers will further enhance the ability of small practices to participate successfully in the Quality Payment Program.

In keeping with the objectives to provide education about the Quality Payment Program and maximize participation, and as mandated by the statute, during a period of 5 years, $100 million in funding was provided for technical assistance to be available to provide guidance and assistance to MIPS eligible clinicians in small practices through contracts with regional health collaboratives, and others. Guidance and assistance on the MIPS performance categories or the transition to APM participation will be available to MIPS eligible clinicians in practices of 15 or fewer clinicians with priority given to practices located in rural areas or medically underserved areas (MUAs), and practices with low MIPS final scores. More information on the technical assistance support available to small practices can be found at *https://qpp.cms.gov/docs/QPP_Support_for_Small_Practices.pdf*.

As discussed in section V.C. of this proposed rule, we have also performed an updated regulatory impact analysis, accounting for flexibilities, many of which are continuing into the Quality Payment Program Year 2, that have been created to ease the burden for small and solo practices. We estimate that at least 80 percent of clinicians in small practices with 1–15 clinicians will receive a positive or neutral MIPS payment adjustment. We refer readers to section V.C. of this proposed rule for details on how this estimate was developed.

3. Summary of Major Provisions for Advanced Alternative Payment Models (Advanced APMs)

a. Overview

APMs represent an important step forward in our efforts to move our healthcare system from volume-based to value-based care. APMs that meet the criteria to be Advanced APMs provide the pathway through which eligible clinicians, who would otherwise fall under the MIPS, can become Qualifying APM Participants (QPs), thereby earning incentive payments for their Advanced APM participation. In the CY 2017 Quality Payment Program final rule (81 FR 77516), we estimated that 70,000 to 120,000 eligible clinicians would be QPs for payment year 2019 based on Advanced APM participation in performance year 2017. With new Advanced APMs expected to be available for participation in 2018, including the Medicare ACO Track 1 Plus (1+) Model, and the reopening of the application process to new participants for some current Advanced APMs, such as the Next Generation ACO Model and Comprehensive Primary Care Plus Model, we anticipate higher numbers of QPs in subsequent years of the program. We currently estimate that approximately 180,000 to 245,000 eligible clinicians may become QPs for payment year 2020 based on Advanced APM participation in performance year 2018.

b. Advanced APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77408), to be considered an Advanced APM, we finalized that an APM must meet all three of the following criteria, as required under section 1833(z)(3)(D) of the Act: (1) The APM must require participants to use CEHRT; (2) The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS and; (3) The APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act.

We are proposing to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the estimated average total Parts A and B revenue of eligible clinicians in participating APM Entities for QP Performance Periods 2019 and 2020.

c. Qualifying APM Participant (QP) and Partial QP Determination

QPs are eligible clinicians in an Advanced APM who have met a threshold for a certain percentage of their patients or payments through an Advanced APM. QPs are excluded from MIPS for the year, and receive a 5 percent APM Incentive Payment for each year they are QPs beginning in 2019 through 2024. The statute sets thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. For Advanced APMs that start or end during the Medicare QP Performance Period and operate

continuously for a minimum of 60 days during the Medicare QP Performance Period for the year, we are proposing to make QP determinations using payment or patient data only for the dates that APM Entities were able to participate in the Advanced APM per the terms of the Advanced APM, not for the full Medicare QP Performance Period. Eligible clinicians who participate in Advanced APMs but do not meet the QP or Partial QP thresholds are subject to MIPS reporting requirements and payment adjustments.

d. All-Payer Combination Option

The All-Payer Combination Option, which uses a calculation based on both the Medicare Option and the eligible clinician's participation in Other Payer Advanced APMs to conduct QP determinations, is applicable beginning in performance year 2019. To become a QP through the All-Payer Combination Option, an eligible clinician must participate in an Advanced APM with CMS, as well as an Other Payer Advanced APM. We identify Other Payer Advanced APMs based on information submitted to us by eligible clinicians, APM Entities, and in some cases by payers, including states and Medicare Advantage Organizations. In addition, the eligible clinician or the APM Entity must submit information to CMS so that we can determine whether other payer arrangements are Other Payer Advanced APMs and whether the eligible clinician meets the requisite QP threshold of participation. To be an Other Payer Advanced APM, as set forth in section 1833(z)(2)(B)(ii) and (C)(ii) of the Act and implemented in the CY 2017 Quality Payment Program final rule, a payment arrangement with a payer (for example, payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payment arrangements in CMS Multi-Payer Models) must meet all three of the following criteria: (1) CEHRT is used; (2) the payment arrangement must require the use of quality measures comparable to those in the quality performance category under MIPS and; (3) the payment arrangement must either require the APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures, or be a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act.

We are proposing modifications pertaining to the third criterion that the payment arrangement must either require the APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures; or be a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act. Specifically, we are proposing to add a revenue-based nominal amount standard in addition to the benchmark-based nominal amount standard that would be applicable only to payment arrangements in which risk is expressly defined in terms of revenue.

We are proposing modifications to our methodologies to determine whether eligible clinicians will meet the QP thresholds using the All-Payer Combination Option. Specifically, we are proposing to conduct all QP determinations under the All-Payer Combination Option at the individual eligible clinician level and are seeking comment on any possible exceptions to this proposed policy that would be warranted, such as a determination based on APM Entity group performance under the All-Payer Combination Option for eligible clinicians participating in CMS Multi-Payer Models. We are also proposing to establish an All-Payer QP Performance Period to assess participation in Other Payer Advanced APMs under the All-Payer Combination Option, and to rename the QP Performance Period we established in rulemaking last year as the Medicare QP Performance Period.

We are proposing to modify the information submission requirements for the All-Payer Combination Option. Specifically, we are proposing modifications to the information we require to make APM Entity or eligible clinician initiated determinations of Other Payer Advanced APMs after the All-Payer QP Performance Period, as well as the information we require to perform QP determinations under the All-Payer Combination Option. We are also proposing policies on the handling of information submitted for purposes of assessment under the All-Payer Combination Option.

We are proposing a Payer Initiated Other Payer Advanced APM Determination Process, which would allow certain other payers, including payment arrangements authorized under Title XIX, Medicare Health Plans, and payers with payment arrangements in CMS Multi-Payer Models, to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 All-Payer QP Performance Period and each year thereafter.

e. Physician-Focused Payment Models (PFPMs)

The PTAC is an 11-member federal advisory committee that is an important avenue for the creation of innovative payment models. The PTAC is charged with reviewing stakeholders' proposed PFPMs, and making comments and recommendations to the Secretary regarding whether they meet the PFPM criteria established by the Secretary through rulemaking in the CY 2017 Quality Payment Program final rule. PTAC comments and recommendations will be reviewed by the CMS Innovation Center and the Secretary, and we will post a detailed response to them on the CMS Web site. We are seeking comments on broadening the definition of PFPM to include payment arrangements that involve Medicaid or the Children's Health Insurance Program (CHIP) as a payer even if Medicare is not included as a payer. This broadened definition might be more inclusive of potential PFPMs that could focus on areas not generally applicable to the Medicare population, and could engage more stakeholders in designing PFPMs. In addition, as we gain experience with public submission of PFPM proposals to the PTAC, we are seeking comments on the Secretary's criteria and stakeholders' needs in developing PFPM proposals aimed at meeting the criteria.

4. Summary of Major Provisions for the Merit-Based Incentive Payment System (MIPS)

For Quality Payment Program Year 2 which is the second year of the MIPS and includes the performance periods in 2018 and the 2020 MIPS payment year, we are proposing the following policies:

a. Quality

We previously finalized that the quality performance category would comprise 60 percent of the final score for the transition year and 50 percent of the final score for the 2020 MIPS payment year (81 FR 77100). For the 2020 MIPS payment year, now we are proposing to maintain a 60 percent weight for the quality performance category contingent upon our proposal to reweight the cost performance category to zero for the 2020 MIPS payment year as discussed in section II.C.6.b.(2) in this proposed rule. Quality measures are selected annually through a call for quality measures, and a final list of quality measures will be published in the **Federal Register** by November 1 of each year. Except as discussed in section II.C.6.b.(3)(a)(iii) of this proposed rule with regard to the

CAHPS for MIPS survey, we are not proposing any changes to the submission criteria for quality measures in this proposed rule. We are proposing for the CAHPS for MIPS survey for the Quality Payment Program Year 2 and future years that the survey administration period would, at a minimum, span over 8 weeks and would end no later than February 28th following the applicable performance period. In addition, we are proposing for the Quality Payment Program Year 2 and future years to remove two Summary Survey Modules (SSM), specifically, ''Helping You to Take Medication as Directed'' and ''Between Visit Communication'' from the CAHPS for MIPS survey.

For the 2018 MIPS performance period, we previously finalized that the data completeness threshold would increase to 60 percent for data submitted on quality measures using QCDRs, qualified registries, via EHR, or Medicare Part B claims. We noted that these thresholds for data submitted on quality measures using QCDRs, qualified registries, via EHR, or Medicare Part B claims would increase for performance periods occurring in 2019 and future years. However, as discussed in section II.C.6.b. of this proposed rule, we are proposing for the 2018 MIPS performance period to maintain the transition year data completeness threshold of 50 percent for data submitted on quality measures using QCDRs, qualified registries, EHR, or Medicare Part B claims to provide an additional year for individual MIPS eligible clinicians and groups to gain experience with the MIPS before increasing the data completeness threshold. However, we are proposing to increase the data completeness threshold for the 2021 MIPS payment year to 60 percent for data submitted on quality measures using QCDRs, qualified registries, EHR, or Medicare Part B claims. We anticipate that for performance periods going forward, as MIPS eligible clinicians gain experience with the MIPS, we would further increase these thresholds over time.

b. Improvement Activities

Improvement activities are those that support broad aims within healthcare delivery, including care coordination, beneficiary engagement, population management, and health equity. In response to comments from experts and stakeholders across the healthcare system, improvement activities were given relative weights of high and medium. For the 2020 MIPS payment year, we previously finalized that the improvement activities performance category would comprise 15 percent of the final score (81 FR 77179). For performance periods occurring in 2018, we are not proposing any changes in improvement activities scoring as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77312).

As discussed in the appendices of this proposed rule, we are proposing new improvement activities (Table F) and improvement activities with changes (Table G) for the 2018 MIPS performance period and future years for inclusion in the Improvement Activities Inventory. Activities proposed in this section would apply for the 2018 MIPS performance period and future performance periods unless further modified via notice and comment rulemaking. We refer readers to Table H of the CY 2017 Quality Payment Program final rule for a list of all the previously finalized improvement activities (81 FR 77817 through 77831).

As discussed in section II.C.6.e.3.(c) of this proposed rule, we are proposing to expand our definition of how we will recognize an individual MIPS eligible clinician or group as being a certified patient-centered medical home or comparable specialty practice. We finalized at § 414.1380(b)(3)(iv) in the CY 2017 Quality Payment Program final rule that a certified patient-centered medical home includes practice sites with current certification from a national program, regional or state program, private payer or other body that administers patient-centered medical home accreditation. We are proposing in section II.C.6.e.(3)(b) of this proposed rule that eligible clinicians in practices that have been randomized to the control group in the CPC+ model would also receive full credit as a Medical Home Model. In addition, for group reporters, for the 2018 MIPS performance period and future performance periods, we are proposing to require that at least 50 percent of the practice sites within a TIN must be recognized as a certified or recognized patient-centered medical home or comparable specialty practice to receive full credit in the improvement activities performance category.

As discussed in section II.C.6.f.(2)(d) of this proposed rule, in recognition of improvement activities as supporting the central mission of a unified Quality Payment Program, we propose to continue to designate activities in the Improvement Activities Inventory that will also qualify for the advancing care information bonus score. This is consistent with our desire to recognize that CEHRT is often deployed to improve care in ways that our programs should recognize.

c. Advancing Care Information

For the Quality Payment Program Year 2, the advancing care information performance category comprises 25 percent of the final score. However, if a MIPS eligible clinician is participating in a MIPS APM the advancing care information performance category may comprise 30 percent or 75 percent of the final score depending on the availability of APM quality data for reporting. Objectives and measures in the advancing care information performance category focus on the secure exchange of health information and the use CEHRT to support patient engagement and improved healthcare quality. While we continue to recommend that physicians and clinicians migrate to the implementation and use of EHR technology certified to the 2015 Edition so they may take advantage of improved functionalities, including care coordination and technical advancements such as application programming interfaces, or APIs, we recognize that some practices may have challenges in adopting new certified health IT. Therefore we are proposing that MIPS eligible clinicians may continue to use EHR technology certified to the 2014 Edition for the performance period in CY 2018. We are proposing minor modifications to the advancing care information objectives and measures and the 2017 advancing care information transition objectives and measures. We are also proposing to add an exclusion for the e-Prescribing and Health Information Exchange Objectives. We are proposing to modify our scoring policy for the Public Health and Clinical Data Registry Reporting Objectives and Measures for the performance score and the bonus score.

We are also proposing to implement several provisions of the 21st Century Cures Act (Pub. L. 114–255, enacted on December 13, 2016) pertaining to hospital-based MIPS eligible clinicians, ambulatory surgical center-based MIPS eligible clinicians, MIPS eligible clinicians using decertified EHR technology, and significant hardship exceptions under the MIPS. We are also proposing to add a significant hardship exception for MIPS eligible clinicians in small practices.

d. Cost

In this proposed rule, we are proposing to weight the cost performance category at zero percent of the final score for the 2020 MIPS payment year in order to improve clinician understanding of the measures

and continue development of episode-based measures that will be used in this performance category.

For the 2018 MIPS performance period, we are proposing to adopt for the cost performance category the total per capita costs for all attributed beneficiaries measure and the Medicare Spending per Beneficiary (MSPB) measure that were adopted for the 2017 MIPS performance period. For the 2018 MIPS performance period, we are not proposing to use the 10 episode-based measures that were adopted for the 2017 MIPS performance period. Although data on the episode-based measures has been made available to clinicians in the past, we are in the process of developing new episode-based measures with significant clinician input and believe it would be more prudent to introduce these new measures over time. We will continue to offer performance feedback on episode-based measures prior to potential inclusion of these measures in MIPS to increase clinician familiarity with the concept as well as specific episode-based measures.

Specifically, we intend to provide feedback on these new episode-based cost measures in the fall of this year for informational purposes only. We intend to provide performance feedback on the MSPB and total per capita cost measures by July 1, 2018, consistent with section 1848(q)(12) of the Act. In addition, we intend to offer feedback on another set of newly developed episode-based cost measures in 2018 as well. Therefore, clinicians would have received feedback on cost measures at several points prior to the cost performance category counting as part of the final score.

e. Submission Mechanisms

As discussed in section II.6.a. of this proposed rule, we are proposing additional flexibility for submitting data. Individual MIPS eligible clinicians or groups would be able to submit measures and activities, as available and applicable, via as many mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories. We expect that this option will provide clinicians the ability to select the measures most meaningful to them, regardless of the submission mechanism.

f. Virtual Groups

There are generally three ways to participate in MIPS: (1) As an individual; (2) as a group; and (3) as a virtual group. In this proposed rule, we are proposing to establish requirements for MIPS participation at the virtual group level. We propose to define a virtual group as a combination of two or more TINs composed of a solo practitioner (a MIPS eligible clinician (as defined at § 414.1305) who bills under a TIN with no other NPIs billing under such TIN) or a group (as defined at § 414.1305) with 10 or fewer eligible clinicians under the TIN that elects to form a virtual group with at least one other such solo practitioner or group for a performance period for a year.

To provide support and reduce burden, we intend to make technical assistance (TA) available, to the extent feasible and appropriate, to support clinicians who choose to come together as a virtual group for the first 2 years of virtual group implementation applicable to the 2018 and 2019 performance years. Clinicians can access the TA infrastructure that they may be already utilizing. For Quality Payment Program Year 3, we intend to provide an electronic election process if technically feasible. Clinicians who do not elect to contact their designated TA representative would still have the option of contacting the Quality Payment Program Service Center. We believe that our proposal will create an election process that is simple and straightforward.

g. MIPS APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77246), we finalized that MIPS eligible clinicians who participate in MIPS APMs will be scored using the APM scoring standard instead of the generally applicable MIPS scoring standard. For the 2018 performance period, we are proposing modifications to the quality performance category reporting requirements and scoring for MIPS eligible clinicians in most MIPS APMs, and other modifications to the APM scoring standard. For purposes of the APM scoring standard, we are proposing to add a fourth snapshot date that would be used only to identify APM Entity groups participating in those MIPS APMs that require full TIN participation. Along with the other APM Entity groups, these APM Entity groups would be used for the purposes of reporting and scoring under the APM scoring standard described the CY 2017 Quality Payment Program final rule (81 FR 77246).

h. Facility-Based Measurement

For the transition year of MIPS, we considered an option for facility-based MIPS eligible clinicians to elect to use their institution's performance rates as a proxy for the MIPS eligible clinician's performance in the quality and cost performance categories. However, we did not propose an option for the transition year of MIPS because there were several operational considerations that needed to be addressed before this option could be implemented. After consideration of comments received on the CY 2017 Quality Payment Program proposed rule (81 FR 28192) and other comments received, we have decided to implement facility-based measures for the 2018 MIPS performance period and future performance periods to add more flexibility for clinicians to be assessed in the context of the facilities at which they work. As discussed in section II.C.7.b. of this proposed rule, we are proposing facility-based measures policies related to applicable measures, applicability to facility-based measurement, group participation, and facility attribution.

For clinicians whose primary professional responsibilities are in a healthcare facility we present a method to assess performance in the quality and cost performance categories of MIPS based on the performance of that facility in another value-based purchasing program. While we propose to limit that opportunity to clinicians who practice primarily in the hospital, we seek to expand the program to other value-based payment programs as appropriate in the future. We discuss that new method of scoring in section II.C.7.b.(4) of this proposed rule.

i. Scoring

In the CY 2017 Quality Payment Program final rule, we finalized a unified scoring system to determine a final score across the 4 performance categories (81 FR 77273 through 77276). For the 2018 MIPS performance period, we propose to build on the scoring methodology we finalized for the transition year, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements.

For quality performance category scoring, we are proposing to extend some of the transition year policies to the 2018 MIPS performance period and are also proposing several modifications to existing policy. For the 2018 MIPS performance period, we are proposing to maintain the 3 point floor for measures that can be reliably scored against a benchmark. We are also proposing, to maintain the policy to assign 3 points to measures that are submitted but do not have a benchmark or do not meet the case minimum, which does not apply to the CMS Web Interface measures and administrative claims based measures. For the 2018 MIPS performance period, we are also proposing to lower the number of points available for measures that do not meet the data completeness

criteria, except for a measure submitted by a small practice, which we propose to continue to assign 3 points if the measure does not meet data completeness. This does not apply to CMS Web Interface measures or administrative claims based measures.

Beginning with the 2018 MIPS performance period, we are proposing to add performance standards for scoring improvement for the quality and cost performance categories. We are also proposing a systematic approach to address topped out quality measures.

For the 2018 MIPS performance period, we are proposing that 3 performance category scores (quality, improvement activities, and advancing care information) would be given weight in the final score, or be reweighted if a performance category score is not available. We are also proposing to add final score bonuses for small practices and for MIPS eligible clinicians that care for complex patients.

We are also proposing that the final score will be compared against a MIPS performance threshold of 15 points, which can be achieved via multiple pathways and continues the gradual transition into MIPS.

j. Performance Feedback

We are proposing to provide Quality Payment Program performance feedback to eligible clinicians and groups. Initially, we would provide performance feedback on an annual basis. In future years, we aim to provide performance feedback on a more frequent basis, which is in line with clinician requests for timely, actionable feedback that they can use to improve care.

k. Targeted Review Process

In the CY 2017 Quality Payment Program final rule (81 FR 77353), we finalized a targeted review process under MIPS wherein a MIPS eligible clinician or group may request that we review the calculation of the MIPS payment adjustment factor and, as applicable, the calculation of the additional MIPS payment adjustment factor applicable to such MIPS eligible clinician or group for a year. We are not proposing any changes to this process for the second year of the MIPS.

l. Third Party Intermediaries

We believe that third party intermediaries that collect or submit data on behalf of individual eligible clinicians and groups participating in MIPS and allowing for flexible reporting options, will provide individual MIPS eligible clinicians and groups with options to accommodate different practices and make measurement meaningful. In the CY 2017 Quality Payment Program final rule (81 FR 77362), we finalized that qualified registries, QCDRs, health IT vendors, and CMS-approved survey vendors will have the ability to act as intermediaries on behalf of individual MIPS eligible clinicians and groups for submission of data to CMS across the quality, improvement activities, and advancing care information performance categories. As discussed in section II.C.10.a.(3) of this proposed rule, we propose to eliminate the self-nomination submission method of email and require that QCDRs and qualified registries submit their self-nomination applications via a web-based tool for future program years beginning with performance periods occurring in 2018. We are proposing, beginning with the 2019 performance period, a simplified process in which existing QCDRs or qualified registries in good standing may continue their participation in MIPS by attesting that their approved data validation plan, cost, approved QCDR measures (applicable to QCDRs only), MIPS quality measures, activities, services, and performance categories offered in the previous year's performance period of MIPS have no changes. QCDRs and qualified registries in good standing, may also make substantive or minimal changes to their approved self-nomination application from the previous year of MIPS that would be submitted during the self-nomination period for CMS review and approval. By attesting that certain aspects of their application will remain the same, as approved from the previous year, existing QCDRs in good standing and qualified registries will be spending less time completing the self-nomination application, as was previously required. This process will be conducted on an annual basis.

In addition, we are proposing that the term ''QCDR measures'' replace the term ''non-MIPS measures,'' without proposing any changes to the definition, criteria, or requirements that were finalized in the CY 2017 Quality Payment Program final rule (81 FR 77375). We are not proposing any changes to the health IT vendors that obtain data from CEHRT requirements.

Lastly, we are proposing for future program years, beginning with performance periods occurring in 2018 that we remove the April 30th survey vendor application deadline. We are proposing for the Quality Payment Program Year 2 and future years that the vendor application deadline be January 31st of the applicable performance year or a later date specified by CMS. We will notify vendors of the application deadline, to become a CMS-approved survey vendor through additional communications and postings.

m. Public Reporting

As discussed in section II.C.11. of this proposed rule, we are proposing public reporting of certain eligible clinician and group Quality Payment Program information, including MIPS and APM data in an easily understandable format as required under the MACRA.

n. Eligibility and Exclusion Provisions of the MIPS Program

In section II.C.1.f. of this proposed rule, we are proposing to modify the definition of a non-patient facing MIPS eligible clinician to apply to virtual groups. We are also proposing to specify that groups considered to be non-patient facing (more than 75 percent of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician) during the non-patient facing determination period would automatically have their advancing care information performance category reweighted to zero. Additionally, in section II.C.3.c. of this proposed rule, we are proposing to modify the low-volume threshold policy established in the CY 2017 Quality Payment Program final rule. As discussed in section II.C.3.c of this proposed rule, we believe that increasing the low-volume threshold to less than or equal to $90,000 in Medicare Part B charges or 200 or fewer Part-B enrolled Medicare beneficiaries would further decrease burden on MIPS eligible clinicians that practice in rural areas or are part of a small practice or are solo practitioners.

E. Payment Adjustments

As discussed in section V.C. of this proposed rule, for the 2020 payment year based on Advanced APM participation in 2018 performance period, we estimate that approximately 180,000 to 245,000 clinicians will become QPs, and therefore be exempt from MIPS and qualify for lump sum incentive payments based on 5 percent of their Part B allowable charges for covered professional services. We estimate that the total lump sum incentive payments will be between approximately $590 and $800 million for the 2020 Quality Payment Program payment year. This expected growth in QPs between the first and second year of the program is due in part to reopening of CPC+ and Next Generation ACO for 2018, and the ACO Track 1+ which is projected to have a large number of participants, with a large majority reaching QP status.

Under the policies in this proposed rule, we estimate that approximately 572,000 eligible clinicians would be required to participate in MIPS in the 2018 MIPS performance period, although this number may vary depending on the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs. After restricting the population to eligible clinician types who are not newly enrolled, the proposed increase in the low-volume threshold is expected to exclude 585,560 clinicians who do not exceed the low-volume threshold. In the 2020 MIPS payment year, MIPS payment adjustments will be applied based on MIPS eligible clinicians' performance on specified measures and activities within three integrated performance categories; the fourth category of cost, as previously outlined, would be weighted to zero in the 2020 MIPS payment year. Assuming that 90 percent of eligible clinicians of all practice sizes participate in MIPS, we estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($173 million) and positive MIPS payment adjustments ($173 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Positive MIPS payment adjustments will also include up to an additional $500 million for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 70 points. These MIPS payment adjustments are expected to drive quality improvement in the provision of MIPS eligible clinicians' care to Medicare beneficiaries and to all patients in the health care system. However, the distribution will change based on the final population of MIPS eligible clinicians for CY 2020 and the distribution of scores under the program. We believe that starting with these modest initial MIPS payment adjustments is in the long-term best interest of maximizing participation and starting the Quality Payment Program off on the right foot, even if it limits the magnitude of MIPS positive adjustments during the 2018 MIPS performance period. The increased availability of Advanced APM opportunities, including through Medical Home models, also provides earlier avenues to earn APM incentive payments for those eligible clinicians who choose to participate.

F. Benefits and Costs of Proposed Rule

The Quality Payment Program may result in quality improvements and improvements to the patients' experience of care as MIPS eligible clinicians respond to the incentives for high-quality care provided by MIPS and implement care quality improvements in their clinical practices.

We also quantify several costs associated with this rule. We estimate that this proposed rule will result in approximately $857 million in collection of information-related burden. We estimate that the incremental collection of information-related burden associated with this proposed rule is approximately $12.4 million relative to the estimated burden of continuing the policies the CY 2017 Quality Payment Program final rule, which is $869 million. We also estimate regulatory review costs of $4.8 million for this proposed rule, comparable to the regulatory review costs of the CY 2017 Quality Payment Program proposed rule. We estimate that federal expenditures will include $173 million in revenue neutral payment adjustments and $500 million for exceptional performance payments. Additional federal expenditures include approximately $590-$800 million in APM incentive payments to QPs.

G. Stakeholder Input

In developing this proposed rule, we sought feedback from stakeholders and the public throughout the process, including in the CY 2017 Quality Payment Program final rule with comment period, listening sessions, webinars, and other listening venues. We received a high degree of interest from a broad spectrum of stakeholders. We thank our many commenters and acknowledge their valued input throughout the rulemaking process. We discuss the substance of relevant comments in the appropriate sections of this proposed rule, though we were not able to address all comments or all issues that all commenters brought forth due to the volume of comments and feedback. In general, commenters continue to support establishment of the Quality Payment Program and maintain optimism as we move from pure FFS Medicare payment towards an enhanced focus on the quality and value of care. Public support for our proposed approach and policies in the proposed rule focused on the potential for improving the quality of care delivered to beneficiaries and increasing value to the public—while rewarding eligible clinicians for their efforts.

We thank stakeholders again for their considered responses throughout our process, in various venues, including comments on the Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (herein referred to as the MIPS and APMs RFI) (80 FR 59102 through 59113) and the CY 2017 Quality Payment Program final rule (81 FR 77008 through 77831). We intend to continue open communication with stakeholders, including consultation with tribes and tribal officials, on an ongoing basis as we develop the Quality Payment Program in future years.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Comments

A. Introduction

The Quality Payment Program, authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is a new approach for reforming care across the health care delivery system for eligible clinicians. Under the Quality Payment Program, eligible clinicians can participate via one of two pathways: Advanced Alternative Payment Models (APMs); or the Merit-based Incentive Payment System (MIPS). We began implementing the Quality Payment Program through rulemaking for calendar year (CY) 2017. This rule provides proposed updates for the second and future years of the Quality Payment Program.

B. Definitions

At § 414.1305, subpart O, we propose to define the following terms:

- All-Payer QP Performance Period.
- Ambulatory Surgical Center (ASC)-based MIPS eligible clinician.
- CMS Multi-Payer Model.
- Full TIN APM.
- Improvement Scoring.
- Medicare QP Performance Period.
- Other MIPS APM.
- Virtual group.

We propose to revise the definitions of the following terms:

- Affiliated practitioner.
- APM Entity.
- Attributed beneficiary.
- Certified Electronic Health Record Technology (CEHRT).
- Final Score.
- Hospital-based MIPS eligible clinician.
- Low-volume threshold.
- Medicaid APM.
- Non-patient facing MIPS eligible clinician.
- Other Payer Advanced APM.
- Rural areas.

We propose to remove the following terms:

- Advanced APM Entity.
- QP Performance Period.

These terms and definitions are discussed in detail in relevant sections of this proposed rule.

C. MIPS Program Details

1. MIPS Eligible Clinicians

a. Definition of a MIPS Eligible Clinician

In the CY 2017 Quality Payment Program final rule (81 FR77040 through 77041), we defined at § 414.1305 a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), and a group that includes such clinicians. We established at § 414.1310(b) and (c) that the following are excluded from this definition per the statutory exclusions defined in section 1848(q)(1)(C)(ii) and (v) of the Act: (1) QPs; (2) Partial QPs who choose not to report on applicable measures and activities that are required to be reported under MIPS for any given performance period in a year; (3) low-volume threshold eligible clinicians; and (4) new Medicare-enrolled eligible clinicians. In accordance with sections 1848(q)(1)(A) and (q)(1)(C)(vi) of the Act, we established at § 414.1310(b)(2) that eligible clinicians (as defined at § 414.1305) who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS. Additionally, we established at § 414.1310(d) that in no case will a MIPS payment adjustment apply to the items and services furnished during a year by eligible clinicians who are not MIPS eligible clinicians, as described in § 414.1310(b) and (c), including those who voluntarily report on applicable measures and activities specified under MIPS.

In the CY 2017 Quality Payment Program final rule (81 FR 77340), we noted that the MIPS payment adjustment applies only to the amount otherwise paid under Part B with respect to items and services furnished by a MIPS eligible clinician during a year, in which we will apply the MIPS payment adjustment at the TIN/NPI level. We have received requests for additional clarifications on which specific Part B services are subject to the MIPS payment adjustment, as well as which Part B services are included for eligibility determinations. We note that when Part B items or services are rendered by suppliers that are also MIPS eligible clinicians, there may be circumstances in which it is not operationally feasible for us to attribute those items or services to a MIPS eligible clinician at an NPI level in order to include them for purposes of applying the MIPS payment adjustment or making eligibility determinations.

To further clarify, there are circumstances that involve Part B prescription drugs and durable medical equipment where the supplier may also be a MIPS eligible clinician. In circumstances in which a MIPS eligible clinician furnishes a Part B covered item or service such as prescribing Part B drugs that are dispensed, administered, and billed by a supplier that is a MIPS eligible clinician, or ordering durable medical equipment that is administered and billed by a supplier that is a MIPS eligible clinician, it is not operationally feasible for us at this time to associate those billed allowable charges with a MIPS eligible clinician at an NPI level in order to include them for purposes of applying the MIPS payment adjustment or making eligibility determinations. For Part B items and services furnished by a MIPS eligible clinician such as purchasing and administering Part B drugs that are billed by the MIPS eligible clinician, such items and services may be subject to MIPS adjustment based on the MIPS eligible clinician's performance during the applicable performance period or included for eligibility determinations. For those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations.

b. Group Practice (Group)

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77088 through 77831), we indicated that we will assess performance either for individual MIPS eligible clinicians or for groups. We defined a group at § 414.1305 as a single Taxpayer Identification Number (TIN) with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their Medicare billing rights to the TIN. We recognize that MIPS eligible clinicians participating in MIPS may be part of a TIN that has one portion of its NPIs participating in MIPS according to the generally applicable scoring criteria while the remaining portion of its NPIs is participating in a MIPS APM or an Advanced APM according to the MIPS APM scoring standard. In the CY 2017 Quality Payment Program final rule (81 FR 77058), we noted that except for groups containing APM participants, we are not permitting groups to ''split'' TINs if they choose to participate in MIPS as a group. Thus, we would like to clarify that we consider a group to be either an entire single TIN or portion of a TIN that: (1) Is participating in MIPS according to the generally applicable scoring criteria while the remaining portion of the TIN is participating in a MIPS APM or an Advanced APM according to the MIPS APM scoring standard; and (2) chooses to participate in MIPS at the group level. Also, we defined an APM Entity group at § 414.1305 as a group of eligible clinicians participating in an APM Entity, as identified by a combination of the APM identifier, APM Entity identifier, TIN, and NPI for each participating eligible clinician.

c. Small Practices

In the CY 2017 Quality Payment Program final rule (81 FR 77188), we defined the term small practices at § 414.1305 as practices consisting of 15 or fewer clinicians and solo practitioners. In section II.C.4.d. of this proposed rule, we discuss how small practice status would apply to virtual groups. Also, in the final rule, we noted that we would not make an eligibility determination regarding the size of small practices, but indicated that small practices would attest to the size of their group practice (81 FR 77057). However, we have since realized that our system needs to account for small practice size in advance of a performance period for operational purposes relating to assessing and scoring the improvement activities performance category, determining hardship exceptions for small practices as proposed in this proposed rule, calculating the small practice bonus for the final score as proposed in this proposed rule, and identifying small practices eligible for technical assistance. As a result, we believe it is critical to modify the way in which small practice size would be determined. To make eligibility determinations regarding the size of small practices for performance periods occurring in 2018 and future years, we propose that CMS would determine the size of small practices as described in this section of the proposed rule. As noted in the CY 2017 Quality Payment

Program final rule, the size of a group (including a small practice) would be determined before exclusions are applied (81 FR 77057). We note that group size determinations are based on the number of NPIs associated with a TIN, which would include clinicians (NPIs) who may be excluded from MIPS participation and do not meet the definition of a MIPS eligible clinician.

To make eligibility determinations regarding the size of small practices for performance periods occurring in 2018 and future years, we propose that CMS would determine the size of small practices by utilizing claims data. For purposes of this section, we are coining the term ''small practice size determination period'' to mean a 12-month assessment period, which consists of an analysis of claims data that spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 30-day claims run out. This would allow us to inform small practices of their status near the beginning of the performance period as it pertains to eligibility relating to technical assistance, applicable improvement activities criteria, the proposed hardship exception for small practices under the advancing care information performance category, and the proposed small practice bonus for the final score.

Thus, for purposes of performance periods occurring in 2018 and the 2020 MIPS payment year, we would identify small practices based on 12 months of data starting from September 1, 2016 to August 31, 2017. We would not change an eligibility determination regarding the size of a small practice once the determination is made for a given performance period and MIPS payment year. We recognize that there may be circumstances in which the small practice size determinations made by CMS do not reflect the real-time size of such practices. We considered two options that could address such potential discrepancies. One option would include an expansion of the proposed small practice size determination period to 24 months with two 12-month segments of data analysis (before and during the performance period), in which CMS would conduct a second analysis of claims data during the performance period. Such an expanded determination period may better capture the real-time size of small practices, but determinations made during the performance period prevent our system from being able to account for the assessment and scoring of the improvement activities performance category and identification of small practices eligible for technical assistance prior to the performance period. Specifically, our system needs to capture small practice determinations in advance of the performance period in order for the system to reflect the applicable requirements for the improvement activities performance category and when a small practice bonus would be applied. A second option would include an attestation component, in which a small practice that was not identified as a small practice during the proposed small practice size determination period would be able to attest to the size of their group practice prior to the performance period. However, this second option would require us to develop several operational improvements, such as a manual process or system that would provide an attestation mechanism for small practices, and a verification process to ensure that only small practices are identified as eligible for technical assistance. Since individual MIPS eligible clinicians and groups are not required to register to participate in MIPS (except for groups utilizing the CMS Web Interface for the Quality Payment Program or administering the CAHPS for MIPS survey), requiring small practices to attest to the size of their group practice prior to the performance period could increase burden on individual MIPS eligible clinicians and groups that are not already utilizing the CMS Web Interface for the Quality Payment Program or administering the CAHPS for MIPS survey. We solicit public comment on the proposal regarding how CMS would determine small practice size.

d. Rural Area and Health Professional Shortage Area Practices

In the CY 2017 Quality Payment Program final rule (81 FR 77188), we finalized at § 414.1380 that for individual MIPS eligible clinicians and groups that are located in rural areas or geographic HPSAs, to achieve full credit under the improvement activities performance category, one high-weighted or two medium-weighted improvement activities are required. In addition, we defined rural areas at § 414.1305 as clinicians in ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available; and Health Professional Shortage Areas (HPSAs) at § 414.1305 as areas designated under section 332(a)(1)(A) of the Public Health Service Act. For technical accuracy purposes, we are proposing to modify the definition of a rural areas at § 414.1305 as ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available. We recognize that there are cases in which an individual MIPS eligible clinician (including a solo practitioner) or a group may have multiple practice sites associated with its TIN and as a result, it is critical for us to outline the application of rural area and HPSA practice designations to such practices. For performance periods occurring in 2017, we consider an individual MIPS eligible clinician or a group with at least one practice site under its TIN in a ZIP code designated as a rural area or HPSA to be a rural area or HPSA practice. For performance periods occurring in 2018 and future years, we believe that a higher threshold than one practice within a TIN is necessary to designate an individual MIPS eligible clinician, a group, or a virtual group as a rural or HPSA practice. We recognize that the establishment of a higher threshold starting in 2018 would more appropriately identify groups and virtual groups with multiple practices under a group's TIN or TINs that are part of a virtual group as rural or HPSA practices and ensure that groups and virtual groups are assessed and scored according to requirements that are applicable and appropriate. We note that in the CY 2017 Quality Payment Program final rule (81 FR 77048 through 77049), we defined a non-patient facing MIPS eligible clinician at § 414.1305 as including a group provided that more than 75 percent of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period. We refer readers to section II.C.1.e. of this proposed rule for our proposal to modify the definition of a non-patient facing MIPS eligible clinician. We believe that using a similar threshold for applying the rural and HPSA designation to an individual MIPS eligible clinician, a group, or virtual group with multiple practices under its TIN or TINs within a virtual group will add consistency for such practices across the MIPS as it pertains to groups and virtual groups obtaining such statuses. Also, we believe that establishing a 75 percent threshold renders an adequate representation of a group or virtual group where a significant portion of a group or a virtual group is identified as having such status. Therefore, for performance periods occurring in 2018 and future

years, we propose that an individual MIPS eligible clinician, a group, or a virtual with multiple practices under its TIN or TINs within a virtual group would be designated as a rural or HPSA practice if more than 75 percent of NPIs billing under the individual MIPS eligible clinician or group's TIN or within a virtual group, as applicable, are designated in a ZIP code as a rural area or HPSA. We solicit public comment on these proposals.

e. Non-Patient Facing MIPS Eligible Clinicians

Section 1848(q)(2)(C)(iv) of the Act requires the Secretary, in specifying measures and activities for a performance category, to give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient. To the extent feasible and appropriate, the Secretary may take those circumstances into account and apply alternative measures or activities that fulfill the goals of the applicable performance category to such non-patient facing MIPS eligible clinicians. In carrying out these provisions, we are required to consult with non-patient facing MIPS eligible clinicians.

In addition, section 1848(q)(5)(F) of the Act allows the Secretary to re-weight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician. We assume many non-patient facing MIPS eligible clinicians will not have sufficient measures and activities applicable and available to report under the performance categories under MIPS. We refer readers to section II.C.6.f.(7) of this proposed rule for the discussion regarding how we address performance category weighting for MIPS eligible clinicians for whom no measures or activities are applicable and available in a given category.

In the CY 2017 Quality Payment Program final rule (81 FR 77048 through 77049), we defined a non-patient facing MIPS eligible clinician for MIPS at § 414.1305 as an individual MIPS eligible clinician that bills 100 or fewer patient-facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the non-patient facing determination period, and a group provided that more than 75 percent of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period. In order to account for the formation of virtual groups starting in the 2018 performance year and how non-patient facing determinations would apply to virtual groups, we need to modify the definition of a non-patient facing MIPS eligible clinician. Therefore, for performance periods occurring in 2018 and future years, we propose to modify the definition of a non-patient facing MIPS eligible clinician at § 414.1305 to mean an individual MIPS eligible clinician that bills 100 or fewer patient-facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the non-patient facing determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or within a virtual group, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period.

We considered a patient-facing encounter to be an instance in which the individual MIPS eligible clinician or group billed for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS. We published the list of patient-facing encounter codes for performance periods occurring in 2017 at *qpp.cms.gov/resources/education*. We intend to publish the list of patient-facing encounter codes for performance periods occurring in 2018 at *qpp.cms.gov* by the end of 2017. The list of patient-facing encounter codes is used to determine the non-patient facing status of MIPS eligible clinicians.

The list of patient-facing encounter codes include two general categories of codes: Evaluation and Management (E&M) codes; and Surgical and Procedural codes. E&M codes capture clinician-patient encounters that occur in a variety of care settings, including office or other outpatient settings, hospital inpatient settings, emergency departments, and nursing facilities, in which clinicians utilize information provided by patients regarding history, present illness, and symptoms to determine the type of assessments to conduct. Assessments are conducted on the affected body area(s) or organ system(s) for clinicians to make medical decisions that establish a diagnosis or select a management option(s).

Surgical and Procedural codes capture clinician-patient encounters that involve procedures, surgeries, and other medical services conducted by clinicians to treat medical conditions. In the case of many of these services, evaluation and management work is included in the payment for the single code instead of separately reported. Patient-facing encounter codes from both of these categories describe direct services furnished by eligible clinicians with impact on patient safety, quality of care, and health outcomes.

For purposes of the non-patient facing policies under MIPS, the utilization of E&M codes and Surgical and Procedural codes allows for accurate identification of patient-facing encounters, and thus accurate eligibility determinations regarding non-patient facing status. As a result, MIPS eligible clinicians considered non-patient facing are able to prepare to meet requirements applicable to non-patient facing MIPS eligible clinicians. We propose to continue applying these policies for purposes of the 2020 MIPS payment year and future years.

As described in the CY 2017 Quality Payment Program final rule, we established the non-patient facing determination period for purposes of identifying non-patient facing MIPS eligible clinicians in advance of the performance period and during the performance period using historical and performance period claims data. This eligibility determination process allows us to begin identifying non-patient facing MIPS eligible clinicians prior to or shortly after the start of the performance period. The non-patient facing determination period is a 24-month assessment period, which includes a two-segment analysis of claims data regarding patient-facing encounters during an initial 12-month period prior to the performance period followed by another 12-month period during the performance period. The initial 12-month segment of the non-patient facing determination period spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 60-day claims run out, which allows us to inform individual MIPS eligible clinicians and groups of their non-patient facing status during the month (December) prior to the start of the performance period. The second 12-month segment of the non-patient facing determination period spans from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year and includes a 60-day claims run out, which will allow us to inform additional individual MIPS eligible clinicians and groups of their non-patient status during the performance period.

However, based on our analysis of data from the initial segment of the non-patient facing determination period for performance periods occurring in 2017 (that is, data spanning from September 1, 2015 to August 31, 2016), we found that it may not be necessary to include a 60-day claims run out since we could achieve a similar outcome for such eligibility determinations by utilizing a 30-day claims run out. In our comparison of data analysis results utilizing a 60-day claims run out versus a 30-day claims run out, there was a 1 percent decrease in data completeness (see Table 1 for data completeness regarding comparative analysis of a 60-day and 30-day claims run out). The small decrease in data completeness would not negatively impact individual MIPS eligible clinicians or groups regarding non-patient facing determinations. We believe that a 30-day claims run out would allow us to complete the analysis and provide such determinations in a more timely manner.

TABLE 1—PERCENTAGES OF DATA COMPLETENESS FOR 60-DAY AND 30-DAY CLAIMS RUN OUT

Incurred year	30-day claims run out*	60-day claims run out*
2015	97.1%	98.4%

* **Note:** Completion rates are estimated and averaged at aggregated service categories and may not be applicable to subsets of these totals. For example, completion rates can vary by provider due to claim processing practices, service mix, and post payment review activity. Completion rates vary from subsections of a calendar year; later portions of a given calendar year will be less complete than earlier ones. Completion rates vary due to variance in loading patterns due to technical, seasonal, policy, and legislative factors. Completion rates are a function of the incurred date used to process claims, and these factors will need to be updated if claims are processed on a claim from date or other methodology.

For performance periods occurring in 2018 and future years, we propose a modification to the non-patient facing determination period, in which the initial 12-month segment of the non-patient facing determination period would span from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and include a 30-day claims run out; and the second 12-month segment of the non-patient facing determination period would span from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year and include a 30-day claims run out. This proposal would only change the duration of the claims run out, not the 12-month timeframes used for the first and second segments of data analysis.

For purposes of the 2020 MIPS payment year, we would initially identify individual MIPS eligible clinicians and groups who are considered non-patient facing MIPS eligible clinicians based on 12 months of data starting from September 1, 2016, to August 31, 2017. To account for the identification of additional individual MIPS eligible clinicians and groups that may qualify as non-patient facing during performance periods occurring in 2018, we would conduct another eligibility determination analysis based on 12 months of data starting from September 1, 2017, to August 31, 2018.

Similarly, for future years, we would conduct an initial eligibility determination analysis based on 12 months of data (consisting of the last 4 months of the calendar year 2 years prior to the performance period and the first 8 months of the calendar year prior to the performance period) to determine the non-patient facing status of individual MIPS eligible clinicians and groups, and conduct another eligibility determination analysis based on 12 months of data (consisting of the last 4 months of the calendar year prior to the performance period and the first 8 months of the performance period) to determine the non-patient facing status of additional individual MIPS eligible clinicians and groups. We would not change the non-patient facing status of any individual MIPS eligible clinician or group identified as non-patient facing during the first eligibility determination analysis based on the second eligibility determination analysis. Thus, an individual MIPS eligible clinician or group that is identified as non-patient facing during the first eligibility determination analysis would continue to be considered non-patient facing for the duration of the performance period and MIPS payment year regardless of the results of the second eligibility determination analysis. We would conduct the second eligibility determination analysis to account for the identification of additional, previously unidentified individual MIPS eligible clinicians and groups that are considered non-patient facing.

Additionally, in the CY 2017 Quality Payment Program final rule (81 FR 77241), we established a policy regarding the re-weighting of the advancing care information performance category for non-patient facing MIPS eligible clinicians. Specifically, MIPS eligible clinicians who are considered to be non-patient facing will have their advancing care information performance category automatically reweighted to zero (81 FR 77241). For groups that are considered to be non-patient facing (that is, more than 75 percent of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician) during the non-patient facing determination period, we are proposing in section II.C.7.b.(3) of this proposed rule to automatically reweight their advancing care information performance category to zero.

We propose to continue applying these policies for purposes of the 2020 MIPS payment year and future years. We solicit public comment on these proposals.

f. MIPS Eligible Clinicians Who Practice in Critical Access Hospitals Billing Under Method II (Method II CAHs)

In the CY 2017 Quality Payment Program final rule (81 FR 77049), we noted that MIPS eligible clinicians who practice in CAHs that bill under Method I (Method I CAHs), the MIPS payment adjustment would apply to payments made for items and services billed by MIPS eligible clinicians, but it would not apply to the facility payment to the CAH itself. For MIPS eligible clinicians who practice in Method II CAHs and have not assigned their billing rights to the CAH, the MIPS payment adjustment would apply in the same manner as for MIPS eligible clinicians who bill for items and services in Method I CAHs. As established in the CY 2017 Quality Payment Program final rule (81 FR 77051), the MIPS payment adjustment will apply to Method II CAH payments under section 1834(g)(2)(B) of the Act when MIPS eligible clinicians who practice in Method II CAHs have assigned their billing rights to the CAH.

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77049 through 77051) for our discussion of MIPS eligible clinicians who practice in Method II CAHs.

g. MIPS Eligible Clinicians Who Practice in Rural Health Clinics (RHCs) or Federally Qualified Health Centers (FQHCs)

As established in the CY 2017 Quality Payment Program final rule (81 FR 77051 through 77053), services rendered by an eligible clinician under the RHC or FQHC methodology, will not be subject to the MIPS payments adjustments. As noted, these eligible clinicians have the option to voluntarily report on applicable measures and activities for MIPS, in which the data received will not be used to assess their

performance for the purpose of the MIPS payment adjustment.

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77051 through 77053) for our discussion of MIPS eligible clinicians who practice in RHCs or FQHCs.

h. MIPS Eligible Clinicians Who Practice in Ambulatory Surgical Centers (ASCs), Home Health Agencies (HHAs), Hospice, and Hospital Outpatient Departments (HOPDs)

Section 1848(q)(6)(E) of the Act provides that the MIPS payment adjustment is applied to the amount otherwise paid under Part B with respect to the items and services furnished by a MIPS eligible clinician during a year. Some eligible clinicians may not receive MIPS payment adjustments due to their billing methodologies. If a MIPS eligible clinician furnishes items and services in an ASC, HHA, Hospice, and/or HOPD and the facility bills for those items and services (including prescription drugs) under the facility's all-inclusive payment methodology or prospective payment system methodology, the MIPS adjustment would not apply to the facility payment itself. However, if a MIPS eligible clinician furnishes other items and services in an ASC, HHA, Hospice, and/or HOPD and bills for those items and services separately, such as under the PFS, the MIPS adjustment would apply to payments made for such items and services. Such items and services would also be considered for purposes of applying the low-volume threshold. Therefore, we propose that services rendered by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology would not be subject to the MIPS payments adjustments. However, these eligible clinicians have the option to voluntarily report on applicable measures and activities for MIPS, in which the data received would not be used to assess their performance for the purpose of the MIPS payment adjustment. We note that eligible clinicians who bill under both the PFS and one of these other billing methodologies (ASC, HHA, Hospice, and/or HOPD) may be required to participate in MIPS if they exceed the low-volume threshold and are otherwise eligible clinicians; in such case, data reported would be used to determine their MIPS payment adjustment. We solicit public comments on this proposal.

i. MIPS Eligible Clinician Identifier

As described in the CY 2017 Quality Payment Program final rule (81 FR 77057), we established that the use of multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or collectively through a group's performance and that the same identifier be used for all four performance categories. While we have multiple identifiers for participation and performance, we established the use of a single identifier, TIN/NPI, for applying the MIPS payment adjustment, regardless of how the MIPS eligible clinician is assessed.

(1) Individual Identifiers

As established in the CY 2017 Quality Payment Program final rule (81 FR 77058), we define a MIPS eligible clinician at § 414.1305 to mean the use of a combination of unique billing TIN and NPI combination as the identifier to assess performance of an individual MIPS eligible clinician. Each unique TIN/NPI combination is considered a different MIPS eligible clinician, and MIPS performance is assessed separately for each TIN under which an individual bills.

(2) Group Identifiers for Performance

As established in the CY 2017 Quality Payment Program final rule (81 FR 77059), we codified the definition of a group at § 414.1305 to mean a group that consists of a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN.

(3) APM Entity Group Identifier for Performance

As described in the CY 2017 Quality Payment Program final rule (81 FR 77060), we established that each eligible clinician who is a participant of an APM Entity is identified by a unique APM participant identifier. The unique APM participant identifier is a combination of four identifiers: (1) APM Identifier (established by CMS; for example, XXXXXX); (2) APM Entity identifier (established under the APM by CMS; for example, AA00001111); (3) TIN(s) (9 numeric characters; for example, XXXXXXXXX); (4) EP NPI (10 numeric characters; for example, 1111111111). We codified the definition of an APM Entity group at § 414.1305 to mean a group of eligible clinicians participating in an APM Entity, as identified by a combination of the APM identifier, APM Entity identifier, TIN, and NPI for each participating eligible clinician.

2. Exclusions

a. New Medicare-Enrolled Eligible Clinician

As established in the CY 2017 Quality Payment Program final rule (81 FR 77061 through 77062), we defined a new Medicare-enrolled eligible clinician at § 414.1305 as a professional who first becomes a Medicare-enrolled eligible clinician within the PECOS during the performance period for a year and had not previously submitted claims under Medicare such as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier. Additionally, we established at § 414.1310(c) that these eligible clinicians will not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year. We established at § 414.1310(d) that in no case would a MIPS payment adjustment apply to the items and services furnished during a year by new Medicare-enrolled eligible clinicians for the applicable performance period.

We used the term ''new Medicare-enrolled eligible clinician determination period'' to refer to the 12 months of a calendar year applicable to the performance period. During the new Medicare-enrolled eligible clinician determination period, we conduct eligibility determinations on a quarterly basis to the extent that is technically feasible to identify new Medicare-enrolled eligible clinicians that would be excluded from the requirement to participate in MIPS for the applicable performance period.

b. Qualifying APM Participant (QP) and Partial Qualifying APM Participant (Partial QP)

In the CY 2017 Quality Payment Program final rule (81 FR 77062), we established at § 414.1305 that a QP (as defined at § 414.1305) is not a MIPS eligible clinician, and is therefore excluded from MIPS. Also, we established that a Partial QP (as defined, at § 414.1305) who does not report on applicable measures and activities that are required to be reported under MIPS for any given performance period in a year is not a MIPS eligible clinician.

c. Low-Volume Threshold

Section 1848(q)(1)(C)(ii)(III) of the Act provides that the definition of a MIPS eligible clinician does not include MIPS eligible clinicians who are below the low-volume threshold selected by the Secretary under section 1848(q)(1)(C)(iv) of the Act for a given year. Section 1848(q)(1)(C)(iv) of the Act requires the Secretary to select a low-volume

threshold to apply for the purposes of this exclusion which may include one or more of the following: (1) The minimum number, as determined by the Secretary, of Part B-enrolled individuals who are treated by the MIPS eligible clinician for a particular performance period; (2) the minimum number, as determined by the Secretary, of items and services furnished to Part B-enrolled individuals by the MIPS eligible clinician for a particular performance period; and (3) the minimum amount, as determined by the Secretary, of allowed charges billed by the MIPS eligible clinician for a particular performance period.

In the CY 2017 Quality Payment Program final rule (81 FR 77069 through 77070), we defined individual MIPS eligible clinicians or groups who do not exceed the low-volume threshold at § 414.1305 as an individual MIPS eligible clinician or group who, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. We established at § 414.1310(b) that for a year, MIPS eligible clinicians who do not exceed the low-volume threshold (as defined at § 414.1305) are excluded from MIPS for the performance period for a given calendar year.

In the CY 2017 Quality Payment Program final rule (81 FR 77069 through 77070), we defined the low-volume threshold determination period to mean a 24-month assessment period, which includes a two-segment analysis of claims data during an initial 12-month period prior to the performance period followed by another 12-month period during the performance period. The initial 12-month segment of the low-volume threshold determination period spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 60-day claims run out, which allows us to inform eligible clinicians and groups of their low-volume status during the month (December) prior to the start of the performance period. The second 12-month segment of the low-volume threshold determination period spans from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year and includes a 60-day claims run out, which allows us to inform additional eligible clinicians and groups of their low-volume status during the performance period.

We recognize that individual MIPS eligible clinicians and groups that are small practices or practicing in designated rural areas face unique dynamics and challenges such as fiscal limitations and workforce shortages, but serve as a critical access point for care and provide a safety net for vulnerable populations. Claims data shows that approximately 15 percent of individual MIPS eligible clinicians (TIN/NPIs) are considered to be practicing in rural areas after applying all exclusions. Also, we have heard from stakeholders that MIPS eligible clinicians practicing in small practices and designated rural areas tend to have a patient population with a higher proportion of older adults, as well as higher rates of poor health outcomes, co-morbidities, chronic conditions, and other social risk factors, which can result in the costs of providing care and services being significantly higher compared to non-rural areas. We also have heard from many solo practitioners and small practices who still face challenges and additional resource burden in participating in the MIPS.

In the CY 2017 Quality Payment Program final rule, we did not establish an adjustment for social risk factors in assessing and scoring performance. In response to the CY 2017 Quality Payment Program final rule, we received public comments indicating that individual MIPS eligible clinicians and groups practicing in designated rural areas would be negatively impacted and at a disadvantage if assessment and scoring methodology did not adjust for social risk factors. Additionally, commenters expressed concern that such individual MIPS eligible clinicians and groups may be disproportionately more susceptible to lower performance scores across all performance categories and negative MIPS payments adjustments, and as a result, such outcomes may further strain already limited fiscal resources and workforce shortages, and negatively impact access to care (reduction and/or elimination of available services).

After the consideration of stakeholder feedback provided during informal listening sessions since the publication of the CY 2017 Quality Payment Program final rule, we are proposing to modify the low-volume threshold policy established in the CY 2017 Quality Payment Program final rule. We believe that increasing the dollar amount and beneficiary count of the low-volume threshold would further reduce the number of eligible clinicians that are required to participate in the MIPS, which would reduce the burden on individual MIPS eligible clinicians and groups practicing in small practices and designated rural areas. Based on our analysis of claims data, we found that increasing the low-volume threshold to to exclude individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to $90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries will exclude approximately 134,000 additional clinicians from MIPS from the approximately 700,000 clinicians that would have been eligible based on the low-volume threshold that was finalized in the CY 2017 Quality Payment Program final rule. Almost half of the additionally excluded clinicians are in small practices and approximately 17 percent are clinicians from practices in designated rural areas. Applying this criterion decreases the percent of the MIPS eligible clinicians that come from small practices. For example, prior to any exclusions, clinicians in small practices represent 35 percent of all clinicians billing Part B services. After applying the eligibility criteria for the CY 2017 Quality Payment Program final rule, MIPS eligible clinicians in small practices represent approximately 27 percent of the clinicians eligible for MIPS; however, with the increased low-volume threshold, approximately 22 percent of the clinicians eligible for MIPS are from small practices. In our analysis, the proposed changes to the low-volume threshold showed little impact on MIPS eligible clinicians from practices in designated rural areas. MIPS eligible clinicians from practices in designated rural areas account for 15 to 16 percent of the total MIPS eligible population. We note that, due to data limitations, we assessed rural status based on the status of individual TIN/NPI and did not model any group definition for practices in designated rural areas.

We believe that increasing the number of such individual eligible clinicians and groups excluded from MIPS participation would reduce burden and mitigate, to the extent feasible, the issue surrounding confounding variables impacting performance under the MIPS. Therefore, beginning with the 2018 MIPS performance period, we are proposing to increase the low-volume threshold. Specifically, at § 414.1305, we are proposing to define an individual MIPS eligible clinician or group who does not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries. This

would mean that 37 percent of individual MIPS eligible clinicians and groups would be in MIPS based on the low-volume threshold exclusion (and the other exclusions). However, 65 percent of Medicare payments would still be captured under MIPS compared to 72.2 percent of Medicare payments under the CY 2017 Quality Payment Program final rule.

We recognize that increasing the dollar amount and beneficiary count of the low-volume threshold would increase the number of individual MIPS eligible clinicians and groups excluded from MIPS. We assessed various levels of increases and found that $90,000 as the dollar amount and 200 as the beneficiary count balances the need to account for individual MIPS eligible clinicians and groups who face additional participation burden while not excluding a significant portion of the clinician population.

MIPS eligible clinicians who do not exceed the low-volume threshold (as defined at § 414.1305) are excluded from MIPS for the performance period with respect to a year. The low-volume threshold also applies to MIPS eligible clinicians who practice in APMs under the APM scoring standard at the APM Entity level, in which APM Entities do not exceed the low-volume threshold. In such cases, the MIPS eligible clinicians participating in the MIPS APM Entity would be excluded from the MIPS requirements for the applicable performance period and not subject to a MIPS payment adjustment for the applicable year. Such an exclusion would not affect an APM Entity's QP determination if the APM Entity is an Advanced APM.

In the CY 2017 Quality Payment Program final rule, we established the low-volume threshold determination period to refer to the timeframe used to assess claims data for making eligibility determinations for the low-volume threshold exclusion (81 FR 77069 through 77070). We defined the low-volume threshold determination period to mean a 24-month assessment period, which includes a two-segment analysis of claims data during an initial 12-month period prior to the performance period followed by another 12-month period during the performance period. Based on our analysis of data from the initial segment of the low-volume threshold determination period for performance periods occurring in 2017 (that is, data spanning from September 1, 2015 to August 31, 2016), we found that it may not be necessary to include a 60-day claims run out since we could achieve a similar outcome for such eligibility determinations by utilizing a 30-day claims run out.

In our comparison of data analysis results utilizing a 60-day claims run out versus a 30-day claims run out, there was a 1 percent decrease in data completeness. The small decrease in data completeness would not substantially impact individual MIPS eligible clinicians or groups regarding low-volume threshold determinations. We believe that a 30-day claims run out would allow us to complete the analysis and provide such determinations in a more timely manner. For performance periods occurring in 2018 and future years, we propose a modification to the low-volume threshold determination period, in which the initial 12-month segment of the low-volume threshold determination period would span from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and include a 30-day claims run out; and the second 12-month segment of the low-volume threshold determination period would span from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year and include a 30-day claims run out. This proposal would only change the duration of the claims run out, not the 12-month timeframes used for the first and second segments of data analysis.

For purposes of the 2020 MIPS payment year, we would initially identify individual eligible clinicians and groups that do not exceed the low-volume threshold based on 12 months of data starting from September 1, 2016 to August 31, 2017. To account for the identification of additional individual eligible clinicians and groups that do not exceed the low-volume threshold during performance periods occurring in 2018, we would conduct another eligibility determination analysis based on 12 months of data starting from September 1, 2017 to August 31, 2018. We would not change the low-volume status of any individual eligible clinician or group identified as not exceeding the low-volume threshold during the first eligibility determination analysis based on the second eligibility determination analysis. Thus, an individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the first eligibility determination analysis would continue to be excluded from MIPS for the duration of the performance period regardless of the results of the second eligibility determination analysis. We established our policy to include two eligibility determination analyses in order to prevent any potential confusion for an individual eligible clinician or group to know whether or not participate in MIPS; also, such policy makes it clear from the onset as to which individual eligible clinicians and groups would be required to participate in MIPS. We would conduct the second eligibility determination analysis to account for the identification of additional, previously unidentified individual eligible clinicians and groups who do not exceed the low-volume threshold. We note that low-volume threshold determinations are made at the individual and group level, and not at the virtual group level.

We note that section 1848(q)(1)(C)(iv) of the Act requires the Secretary to select a low-volume threshold to apply for the purposes of this exclusion which may include one or more of the following: (1) The minimum number, as determined by the Secretary, of Part B-enrolled individuals who are treated by the MIPS eligible clinician for a particular performance period; (2) the minimum number, as determined by the Secretary, of items and services furnished to Part B-enrolled individuals by the MIPS eligible clinician for a particular performance period; and (3) the minimum amount, as determined by the Secretary, of allowed charges billed by the MIPS eligible clinician for a particular performance period. We have established a low-volume threshold that accounts for the minimum number of Part-B enrolled individuals who are treated by a MIPS eligible clinician and that accounts for the minimum amount of allowed charges billed by a MIPS eligible clinician. We have not made proposals specific to a minimum number of items and service furnished to Part-B enrolled individuals by a MIPS eligible clinician.

In order to expand the ways in which claims data could be analyzed for purposes of determining a more comprehensive assessment of the low-volume threshold, we have assessed the option of establishing a low-volume threshold for items and services furnished to Part-B enrolled individuals by a MIPS eligible clinician. We have considered defining items and services by using the number of patient encounters or procedures associated with a clinician. Defining items and services by patient encounters would assess each patient per visit or encounter with the MIPS eligible clinician. We believe that defining items and services by using the number of patient encounters or procedures is a simple and straightforward approach for stakeholders to understand. However,

we are concerned that using this unit of analysis could incentivize clinicians to focus on volume of services rather than the value of services provided to patients. Defining items and services by procedure would tie a specific clinical procedure rendered to a patient to a clinician. We solicit public comment on the methods of defining items and services furnished by clinicians described above and alternate methods of defining items and services.

For the individual MIPS eligible clinicians and groups that would be excluded from MIPS participation as a result of an increased low-volume threshold, we believe that in future years it would be beneficial to provide, to the extent feasible, such individual MIPS eligible clinicians and groups with the option to opt-in to MIPS participation if they might otherwise be excluded under the low-volume threshold such as where they only meet one of the threshold determinations (including a third determination based on Part B items and services, if established). For example, if a clinician meets the low-volume threshold of $90,000 in allowed charges, but does not meet the threshold of 200 patients or, if established, the threshold pertaining to Part B items and services, we believe the clinician should, to the extent feasible, have the opportunity to choose whether or not to participate in the MIPS and be subject to MIPS payment adjustments. We recognize that this choice would present additional complexity to clinicians in understanding all of their available options and may impose additional burden on clinicians by requiring them to notify CMS of their decision. Because of these concerns and our desire to establish options in a way that is a low-burden and user-focused experience for all MIPS eligible clinicians, we would not be able to offer this additional flexibility until performance periods occurring in 2019. Therefore, as a means of expanding options for clinicians and offering them the ability to participate in MIPS if they otherwise would not be included, for the purposes of the 2021 MIPS payment year, we propose to provide clinicians the ability to opt-in to the MIPS if they meet or exceed one, but not all, of the low-volume threshold determinations, including as defined by dollar amount, beneficiary count or, if established, items and services. We request public comment on this proposal.

We note that there may be additional considerations we should address for scenarios in which an individual eligible clinician or a group does not exceed the low-volume threshold and opts-in to participate in MIPS. We therefore seek comment on any additional considerations we should address when establishing this opt-in policy. Such as, should we establish parameters for individual clinicians or groups who elect to opt-in to participate in MIPS such as required length of participation? Additionally, we note that there is the potential with this opt-in policy for there to be an impact on our ability to create quality benchmarks that meet our sample size requirements. For example, if particularly small practices or solo practitioners with low Part B beneficiary volumes opt-in, such clinician's may lack sufficient sample size to be scored on many quality measures, especially measures that do not apply to all of a MIPS eligible clinician's patients. We therefore seek comment on how to address any potential impact on our ability to create quality benchmarks that meet our sample size requirements.

We solicit public comments on these proposals.

3. Group Reporting

a. Background

As described in the CY 2017 Quality Payment Program final rule, we established the following requirements for groups (81 FR 77072):

- Individual eligible clinicians and individual MIPS eligible clinicians will have their performance assessed as a group as part of a single TIN associated with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by a NPI, who have reassigned their Medicare billing rights to the TIN (at § 414.1310(e)(1)).
- A group must meet the definition of a group at all times during the performance period for the MIPS payment year in order to have its performance assessed as a group (at § 414.1310(e)(2)).
- Individual eligible clinicians and individual MIPS eligible clinicians within a group must aggregate their performance data across the TIN to have their performance assessed as a group (at § 414.1310(e)(3)).
- A group that elects to have its performance assessed as a group will be assessed as a group across all four MIPS performance categories (at § 414.1310(e)(4)).

As noted in the CY 2017 Quality Payment Program final rule, we would not make an eligibility determination regarding group size, but indicated that groups would attest to their group size for purpose of using the CMS Web Interface or a group identifying as a small practice (81 FR 77057). In section II.C.1.d. of this proposed rule, we are proposing to modify the way in which size would be determined for small practices by establishing a process under which CMS would utilize claims data to make small practice size determinations. Also, in section II.C.4.e. of this proposed rule, we are proposing to establish a policy under which CMS would utilize claims data to determine group size for groups of 10 or fewer eligible clinicians seeking to form or join a virtual group.

As noted in the CY 2017 Quality Payment Program final rule, a group size would be determined before exclusions are applied (81 FR 77057). We note that group size determinations are based on the number of NPIs associated with a TIN, which would include clinicians (NPIs) who may be excluded from MIPS participation and do not meet the definition of a MIPS eligible clinician.

b. Registration

As described in the CY 2017 Quality Payment Program final rule (81 FR 77072 through 77073), we established, the following policies:

- A group must adhere to an election process established and required by CMS (§ 414.1310(e)(5)), which includes:

++ Groups will not be required to register to have their performance assessed as a group except for groups submitting data on performance measures via participation in the CMS Web Interface or groups electing to report the CAHPS for MIPS survey for the quality performance category. For all other data submission mechanisms, groups must work with appropriate third party intermediaries as necessary to ensure the data submitted clearly indicates that the data represent a group submission rather than an individual submission.

++ In order for groups to elect participation via the CMS Web Interface or administration of the CAHPS for MIPS survey, such groups must register by June 30 of the applicable performance period (that is, June 30, 2018, for performance periods occurring in 2018). We note that groups participating in APMs that require APM Entities to report using the CMS Web Interface are not required to register for the CMS Web Interface or administer the CAHPS for MIPS survey separate from the APM.

When groups submit data utilizing third party intermediaries, such as a qualified registry, QCDR, or EHR, we are able to obtain group information from the third party intermediary and discern whether the data submitted represents group submission or individual submission once the data are submitted.

In the CY 2017 Quality Payment Program final rule (81 FR 77072 through 77073), we discussed the implementation of a voluntary registration process if technically feasible. Since the publication of the CY 2017 Quality Payment Program final rule, we have determined that it is not technically feasible to develop and build a voluntary registration process. Until further notice, we are not implementing a voluntary registration process.

Also, in the CY 2017 Quality Payment Program final rule (81 FR 77075), we expressed our commitment to pursue the active engagement of stakeholders throughout the process of establishing and implementing virtual groups. We received public comments in response to the CY 2017 Quality Payment Program final rule and additional stakeholder feedback by hosting several virtual group listening sessions and convening user groups. Many stakeholders requested that CMS provide an option that would permit a portion of a group to participate in MIPS outside the group by reporting as a separate subgroup or forming a virtual group. Stakeholders indicated that the option would measure performance more effectively, enable groups to identify areas for improvement at a granular level that would further improve quality of care and health outcomes, and increase coordination of care.

We recognize that groups, including multi-specialty groups, have requested over the years that we make an option available to them that would allow a portion of a group to report as a separate subgroup on measures and activities that are more applicable to the subgroup and be assessed and scored accordingly based on the performance of the subgroup. In future rulemaking, we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a subgroup level and create such functionality through a new identifier. We solicit public comment on the ways in which participation in MIPS at the subgroup level could be established.

4. Virtual Groups

a. Background

There are generally three ways to participate in MIPS: (1) Individual-level reporting; (2) group-level reporting; and (3) virtual group-level reporting. We refer readers to sections II.C.1., II.C.3., and II.C.5. of this proposed rule for a discussion of the previously established requirements for individual- and group-level participation and our proposed policies for performance periods occurring in 2018 and future years. In this rule, we are proposing to establish requirements for MIPS participation at the virtual group level.

Section 1848(q)(5)(I) of the Act provides for the use of voluntary virtual groups for certain assessment purposes, including the election of practices to be a virtual group and the requirements for the election process. Section 1848(q)(5)(I)(i) of the Act provides that MIPS eligible clinicians electing to be a virtual group must: (1) Have their performance assessed for the quality and cost performance categories in a manner that applies the combined performance of all the MIPS eligible clinicians in the virtual group to each MIPS eligible clinician in the virtual group for the applicable performance period; and (2) be scored for the quality and cost performance categories based on such assessment. Section 1848(q)(5)(I)(ii) of the Act requires, in accordance with section 1848(q)(5)(I)(iii) of the Act, the establishment and implementation of a process that allows an individual MIPS eligible clinician or a group consisting of not more than 10 MIPS eligible clinicians to elect, for a given performance period, to be a virtual group with at least one other such individual MIPS eligible clinician or group. The virtual group may be based on appropriate classifications of providers, such as by geographic areas or by provider specialties defined by nationally recognized specialty boards of certification or equivalent certification boards.

Section 1848(q)(5)(I)(iii) of the Act provides that the virtual group election process must include the following requirements: (1) An individual MIPS eligible clinician or group electing to be in a virtual group must make their election prior to the start of the applicable performance period and cannot change their election during the performance period; (2) an individual MIPS eligible clinician or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group; (3) a virtual group is a combination of TINs; (4) the requirements must provide for formal written agreements among individual MIPS eligible clinicians and groups electing to be a virtual group; and (5) such other requirements as the Secretary determines appropriate.

b. Definition of a Virtual Group

As noted above, section 1848(q)(5)(I)(ii) of the Act requires, in accordance with section 1848(q)(5)(I)(iii) of the Act, the establishment and implementation of a process that allows an individual MIPS eligible clinician or group consisting of not more than 10 MIPS eligible clinicians to elect, for a given performance period, to be a virtual group with at least one other such individual MIPS eligible clinician or group. Given that section 1848(q)(5)(I)(iii)(V) of the Act provides that a virtual group is a combination of TINs, we interpret the references to an ''individual'' MIPS eligible clinician in section 1848(q)(5)(I)(ii) of the Act to mean a solo practitioner, which, for purposes of section 1848(q)(5)(I) of the Act, we propose to define as a MIPS eligible clinician (as defined at § 414.1305) who bills under a TIN with no other NPIs billing under such TIN.

Also, we recognize that a group (TIN) may include not only NPIs who meet the definition of a MIPS eligible clinician, but also NPIs who do not meet the definition of a MIPS eligible clinician at § 414.1305 and who are excluded from MIPS under § 414.1310(b) or (c) based on one of four exclusions (new Medicare-enrolled eligible clinician; QP; Partial QP who chooses not to report on measures and activities under MIPS; and eligible clinicians that do not exceed the low-volume threshold). Thus, we interpret the references to a group ''consisting of not more than 10'' MIPS eligible clinicians in section 1848(q)(5)(I)(ii) of the Act to mean that a group with 10 or fewer eligible clinicians (as defined at § 414.1305) would be eligible to form or join a virtual group. For purposes of the MIPS payment adjustment, the adjustment would apply only to NPIs in the virtual group who meet the definition of a MIPS eligible clinician at § 414.1305 and who are not excluded from MIPS under § 414.1310(b) or (c). We note that such groups, as defined at § 414.1305, would need to include at least one MIPS eligible clinician in order to be eligible to join or form a virtual group. We refer readers to section II.C.4.g. of this proposed rule for discussion regarding the assessment and scoring of groups participating in MIPS as a virtual group.

We propose to define a virtual group at § 414.1305 as a combination of two or more TINs composed of a solo practitioner (a MIPS eligible clinician (as defined at § 414.1305) who bills under a TIN with no other NPIs billing under such TIN), or a group (as defined at § 414.1305) with 10 or fewer eligible clinicians under the TIN that elects to form a virtual group with at least one

other such solo practitioner or group for a performance period for a year.

Lastly, we note that qualifications as a virtual group for purposes of MIPS do not change the application of the physician self-referral law to a financial relationship between a physician and an entity furnishing designated health services, nor does it change the need for such a financial relationship to comply with the physician self-referral law.

We note that while entire TINs participate in a virtual group, including each NPI under a TIN, and are assessed and scored collectively as a virtual group, only NPIs that meet the definition of a MIPS eligible clinician would be subject to a MIPS payment adjustment. However, we note that, as discussed in section II.C.4.h. of this proposed rule, any MIPS eligible clinician who is part of a TIN participating in a virtual group and participating in a MIPS APM or Advanced APM under the MIPS APM scoring standard would not receive a MIPS payment adjustment based on the virtual group's final score, but would receive a payment adjustment based on the MIPS APM scoring standard.

Additionally, we recognize that there are circumstances in which a TIN may have one portion of its NPIs participating under the generally applicable MIPS scoring criteria while the remaining portion of NPIs under the TIN is participating in a MIPS APM or an Advanced APM under the MIPS APM scoring standard. In the CY 2017 Quality Payment Program final rule (81 FR 77058), we noted that except for groups containing APM participants, we are not permitting groups to ''split'' TINs if they choose to participate in MIPS as a group (81 FR 77058). Thus, we consider a group to mean an entire single TIN that elects to participate in MIPS at the group or virtual group level, including groups that have a portion of its NPIs participating in a MIPS APM or an Advanced APM. We note that such groups would participate in MIPS similar to other groups.

To clarify, for all groups, including groups containing participants in a MIPS APM or an Advanced APM, the group's performance assessment consists of the entire TIN regardless of whether the group participates in MIPS as part of a virtual group. Generally, for groups other than groups containing participants in a MIPS APM or an Advanced APM, each MIPS eligible clinician under the TIN (TIN/NPI) receives a MIPS adjustment based on the entire group's performance assessment (entire TIN). For groups containing participants in a MIPS APM or an Advanced APM, only the portion of the TIN that is being scored for MIPS according to the generally applicable scoring criteria (TIN/NPI) receives a MIPS adjustment based on the entire group's performance assessment (entire TIN). The remaining portion of the TIN that is being scored according to the APM scoring standard (TIN/NPI) receives a MIPS adjustment based on that standard, or may be exempt from MIPS if they achieve QP or Partial QP status.

We propose to apply a similar policy to groups, including groups containing participants in a MIPS APM or an Advanced APM, that are participating in MIPS as part of a virtual group. Specifically, for groups other than groups containing participants in a MIPS APM or an Advanced APM, each MIPS eligible clinician (TIN/NPI) would receive a MIPS adjustment based on the virtual group's combined performance assessment (combination of TINs). For groups containing participants in a MIPS APM or an Advanced APM, only the portion of the TIN that is being scored for MIPS according to the generally applicable scoring criteria (TIN/NPI) would receive a MIPS adjustment based on the virtual group's combined performance assessment (combination of TINs). As discussed in section II.C.4.h. of this proposed rule, we are proposing to use waiver authority to ensure that any participants in the group who are participating in a MIPS APM receive their payment adjustment based on their score under the APM scoring standard (TIN/NPI). Such participants may be exempt from MIPS if they achieve QP or Partial QP status.

We refer readers to section II.C.4.e. of this proposed rule for a discussion of the proposed virtual group election process and section II.C.4.g. of this proposed rule for discussion of our proposals regarding the assessment and scoring of virtual groups.

We recognize that virtual groups would each have unique characteristics and varying patient populations. As noted in section II.C.4.a. of this proposed rule, the statute provides the Secretary with discretion to establish appropriate classifications regarding the composition of virtual groups such as by geographic area or specialty. However, we believe it is important for virtual groups to have the flexibility to determine their own composition at this time, and, as a result, we are not proposing to establish any such classifications regarding virtual group composition. We further note that the statute does not limit the number of TINs that may form a virtual group, and we are not proposing to establish such a limit at this time. We did consider however proposing to establish such a limit, such as 50 or 100 participants. In particular, we are concerned that virtual groups of too substantial a size (for example, 10 percent of all MIPS eligible clinicians in a given specialty or sub-specialty) may make it difficult to compare performance between and among clinicians. We believe that limiting the number of virtual group participants could eventually assist virtual groups as they aggregate their performance data across the virtual group. However, we believe that as we initially implement virtual groups, it is important for virtual groups to have the flexibility to determine their own size, and thus, a better approach is to not place such a limit on virtual group size. We will, however, monitor the ways in which solo practitioners and groups with 10 or fewer eligible clinicians form virtual groups and may propose to establish appropriate classifications regarding virtual group composition or a limit on the number of TINs that may form a virtual group in future rulemaking as necessary. We solicit public comment on these proposals, as well as our approach of not establishing appropriate classifications (such as classification by geographic area or specialty) regarding virtual group composition or a limit on the number of TINs that may form a virtual group at this time.

In the CY 2017 Quality Payment Program final rule (81 FR 77073 through 77077), we expressed our commitment to pursue the active engagement of stakeholders throughout the process of establishing and implementing virtual groups. We received public comments in response to the CY 2017 Quality Payment Program final rule and additional stakeholder feedback by hosting several virtual group listening sessions and convening user groups. Many stakeholders requested that CMS provide an option that would permit a portion of a group to participate in MIPS outside the group by reporting separately or forming a virtual group. We refer readers to section II.C.b.3. of this proposed rule for discussion regarding a potential option for addressing such issue.

c. MIPS Virtual Group Identifier for Performance

To ensure that we have accurately captured all of the MIPS eligible clinicians participating in a virtual group, we propose that each MIPS eligible clinician who is part of a virtual group would be identified by a unique virtual group participant identifier. The unique virtual group participant

identifier would be a combination of three identifiers: (1) Virtual group identifier (established by CMS; for example, XXXXXX); (2) TIN (9 numeric characters; for example, XXXXXXXXX); and (3) NPI (10 numeric characters; for example, 1111111111). For example, a virtual participant identifier could be VG–XXXXXX, TIN–XXXXXXXXX, NPI–11111111111. We solicit public comment on this proposal.

d. Application of MIPS Group Policies to Virtual Groups

In the CY 2017 Quality Payment Program final rule (81 FR 77070 through 77072), we finalized various requirements for groups under MIPS at § 414.1310(e), under which groups electing to report at the group level are assessed and scored across the TIN for all four performance categories. We propose to apply our previously finalized and proposed group policies to virtual groups, unless otherwise specified. We recognize that there are instances in which we may need to clarify or modify the application of certain previously finalized or proposed group-related policies to virtual groups, such as the definition of a non-patient facing MIPS eligible clinician; small practice, rural area and HPSA designations; and groups that have a portion of its NPIs participating in a MIPS APM or an Advanced APM (see section II.C.4.b. of this proposed rule). More generally, such policies may include those that require a calculation of the number of NPIs across a TIN (given that a virtual group is a combination of TINs), the application of any virtual group participant's status or designation to the entire virtual group, and the applicability and availability of certain measures and activities to any virtual group participant and to the entire virtual group.

With regard to the applicability of the non-patient facing policies to virtual groups, in the CY 2017 Quality Payment Program final rule (81 FR 77048 through 77049), we defined the term non-patient facing MIPS eligible clinician at § 414.1305 as an individual MIPS eligible clinician that bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the non-patient facing determination period, and a group provided that more than 75 percent of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period. We are proposing to modify the definition of a non-patient facing MIPS eligible clinician to include clinicians in a virtual group provided that more than 75 percent of the NPIs billing under the virtual group's TINs meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period. We refer readers to section II.C.4.f. of this rule for the proposed modification. We note that other policies previously established and proposed in this proposed rule for non-patient facing groups would apply to virtual groups. For example, as discussed in section II.C.1.e. of this proposed rule, virtual groups determined to be non-patient facing would have their advancing care information performance category automatically reweighted to zero.

In regard to the application of small practice status to virtual groups, we are proposing that a virtual group would be identified as having a small practice status if the virtual group does not have 16 or more members of a virtual group (NPIs). We refer readers to section II.C.4.d. of this proposed rule for discussion regarding how small practice status would apply to virtual groups for scoring under MIPS. In the CY 2017 Quality Payment Program final rule (81 FR 77188), we defined the term small practices at § 414.1305 as practices consisting of 15 or fewer clinicians and solo practitioners. In section II.C.1.c. of this proposed rule, we are proposing for performance periods occurring in 2018 and future years to identify small practices by utilizing claims data. For performance periods occurring in 2018, we would identify small practices based on 12 months of data starting from September 1, 2016 to August 31, 2017.

In section II.C.1.e. of this rule, we propose to determine rural area and HPSA practice designations for groups participating in MIPS at the group level. We note that in section II.C.7.b we describe our scoring proposals for practices that are in a rural area or HPSA practice. For performance periods occurring in 2018 and future years, we are proposing that a group with 75 percent or more of the TIN's practice sites designated as rural areas or HPSA practices would be designated as a rural area or HPSA at the group level. We are proposing that a virtual group with 75 percent or more of the virtual group's TINs designated as rural areas or HPSA practices would be designated as a rural area or HPSA practice at the virtual group level. We note that other policies previously established and proposed in this proposed rule for rural area and HPSA groups would apply to virtual groups.

We recognize that the measures and activities available to groups would also be available to virtual groups. Virtual groups would be required to meet the reporting requirements for each measure and activity, and the virtual group would be responsible for ensuring that their measures and activities are aggregated across the virtual group (for example, across their TINs). We note that other previously established group-related policies and proposed policies in this proposed rule pertaining to the four performance categories would apply to virtual groups.

Therefore, we propose to apply MIPS group policies to virtual groups except as otherwise specified. We solicit public comment on this proposal. We are also interested on receiving feedback on how such group-related policies previously established and proposed in this proposed rule either would or would not apply to virtual groups. In addition, we request public comment on any other policies that may need to be clarified or modified with respect to virtual groups, such as those that require a calculation of the number of NPIs across a TIN (given that a virtual group is a combination of TINs), the application of any virtual group participant's status or designation to the entire virtual group, the application of the group reporting requirements for the individual performance categories to virtual groups, and the applicability and availability of certain measures and activities to any virtual group participant and to the entire virtual group.

e. Election Process

As noted above, section 1848(q)(5)(I)(iii)(I) and (II) of the Act provides that the virtual group election process must include certain requirements, including that: (1) An individual MIPS eligible clinician or group electing to be in a virtual group must make their election prior to the start of the applicable performance period and cannot change their election during the performance period; and (2) an individual MIPS eligible clinician or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group. We propose to codify at § 414.1315(a) that a solo practitioner or a group of 10 or fewer eligible clinicians must make their election prior to the start of the applicable performance period and cannot change their election during the performance period. Virtual group participants may elect to be in no more than one virtual group for a performance period and, in the case of a group, the election applies to all MIPS eligible

clinicians in the group. For the 2018 performance year and future years, we are proposing to establish an election period.

We propose to codify at § 414.1315(b) that, beginning with performance periods occurring in 2018, a solo practitioner, or group of 10 or fewer eligible clinicians electing to be in a virtual group must make their election by December 1 of the calendar year preceding the applicable performance period. For example, a solo practitioner or group would need to make their election by December 1, 2017 to participate in MIPS as a virtual group during the 2018 performance period. Prior to the election deadline, a virtual group representative would have the opportunity to make an election, on behalf of the members of a virtual group, regarding the formation of a virtual group for an applicable performance period. We intend to publish the beginning date of the virtual group election period applicable to the 2018 performance period and future years in subregulatory guidance.

In order to provide support and reduce burden, we intend to make technical assistance (TA) available, to the extent feasible and appropriate, to support clinicians who choose to come together as a virtual group. Clinicians can access TA infrastructure and resources that they may already be utilizing). For Quality Payment Program year 3, we intend to provide an electronic election process if technically feasible. We propose that clinicians who do not elect to contact their designated TA representative would still have the option of contacting the Quality Payment Program Service Center.

We propose to codify at § 414.1315(c) a two-stage virtual group election process, stage 1 of which is optional, for the applicable 2018 and 2019 performance periods. Stage 1 pertains to virtual group eligibility determinations. In stage 1, solo practitioners and groups with 10 or fewer eligible clinicians interested in forming or joining a virtual group would have the option to contact their designated TA representative or the Quality Payment Program Service Center in order to obtain information pertaining to virtual groups and/or determine whether or not they are eligible, as it relates to the practice size requirement of a solo practitioner or a group of 10 or fewer eligible clinicians, to participate in MIPS as a virtual group (§ 414.1315(a)(1)(i)). We note that activity involved in stage 1 is not required, but a resource available to solo practitioners and groups with 10 or fewer eligible clinicians; otherwise, solo practitioners or groups with 10 or fewer eligible clinicians that do not engage in any activity during stage 1, they would begin the election process at stage 2. For solo practitioners and groups who engage in stage 1 and were determined eligible for virtual group participation, they would proceed to stage 2. Engaging in stage 1 would provide solo practitioners and groups with the option to confirm whether or not they are eligible to join or form a virtual group before going to the lengths of executing formal written agreements, submitting a formal election registration, allocating resources for virtual group implementation, and other related activities; whereas, engaging directly in stage 2 as an initial step, solo practitioners and groups may have conducted all such efforts to only have their election registration be rejected with no recourse or remaining time to amend and resubmit.

During stage 1 of the virtual group election process, we would determine whether or not a TIN is eligible to form or join a virtual group. In order for a solo practitioner to be eligible to form or join a virtual group, the solo practitioner would need to be considered a MIPS eligible clinician (defined at § 414.1305) who bills under a TIN with no other NPIs billing under such TIN, and not excluded from MIPS under § 414.1310(b) and (c). In order for a group to be eligible to form or join a virtual group, a group would need to have a TIN size that does not exceed 10 eligible clinicians and not excluded from MIPS based on the low-volume threshold exclusion at the group level. For purposes of determining TIN size for virtual group participation eligibility, we coin the term ''virtual group eligibility determination period'' and define it to mean an analysis of claims data during an assessment period of up to five months that would begin on July 1 and end as late as November 30 of a calendar year prior to the performance year and includes a 30-day claims run out.

To capture a real-time representation of TIN size, we propose to analyze up to five months of claims data on a rolling basis, in which virtual group eligibility determinations for each TIN would be updated and made available monthly. We note that an eligibility determination regarding TIN size is based on a relative point in time within the five-month virtual group eligibility determination period, and not an eligibility determination made at the end of such five-month determination period. If at any time a TIN is determined to be eligible to participate in MIPS as part of a virtual group, the TIN would retain that status for the duration of the election period and the applicable performance period. TINs could determine their status by contacting their designated TA representative or the Quality Payment Program Service Center; otherwise, the TIN's status would be determined at the time that the TIN's virtual group election is submitted. For example, if a group contacted their designated TA representative or the Quality Payment Program Service Center on October 20, 2017, the claims data analysis would include the months of July through September of 2017, and if determined not to exceed 10 eligible clinicians, such TIN's size status would be identified at such time and would be retained for the duration of the election period and the 2018 performance period. If another group contacted their designated TA representative or the Quality Payment Program Service Center on November 20, 2017, the claims data analysis would include the months of July through October of 2017, and if determined not to exceed 10 eligible clinicians, such TIN's size status would be identified at such time and would be retained for the duration of the election period and the 2018 performance period.

We believe such a virtual group determination period process provides a relative representation of real-time group size for purposes of virtual group eligibility and allows groups to know their real-time size status immediately and plan accordingly for virtual group implementation. It is anticipated that starting in September of each calendar year prior to the applicable performance year beginning in 2018, groups would be able to contact their designated TA representative or the Quality Payment Program Service Center and inquire about virtual group participation eligibility. We note that TIN size determinations are based on the number of NPIs associated with a TIN, which would include clinicians (NPIs) excluded from MIPS participation and who do not meet the definition of a MIPS eligible clinician.

For groups that do not choose to participate in stage 1 of the election process (that is, the group does not request an eligibility determination), we will make an eligibility determination during stage 2 of the election process. If a group began the election process at stage 2 and if its TIN size is determined not to exceed 10 eligible clinicians and not excluded based on the low-volume threshold exclusion at the group level, the group is determined eligible to participate in MIPS as part of a virtual group, and such virtual group eligibility determination status would be retained

for the duration of the election period and applicable performance period.

Stage 2 pertains to virtual group formation. For stage two, we propose the following:

- TINs comprising a virtual group must establish a written formal agreement between each member of a virtual group prior to an election (§ 414.1315(c)(2)(i)).
- On behalf of a virtual group, the official designated virtual group representative must submit an election by December 1 of the calendar year prior to the start of the applicable performance period. (§ 414.1315(c)(2)(ii)). We anticipate this election will occur via email to the Quality Payment Program Service Center using the following email address: *MIPS_VirtualGroups@cms.hhs.gov*.
- The submission of a virtual group election must include, at a minimum, information pertaining to each TIN and NPI associated with the virtual group and contact information for the virtual group representative (§ 414.1315(c)(2)(iii). A virtual group representative would submit the following type of information: each TIN associated with the virtual group; each NPI associated with a TIN that is part of the virtual group; name of the virtual group representative; affiliation of the virtual group representative to the virtual group; contact information for the virtual group representative; and confirm through acknowledgment that a written formal agreement has been established between each member of the virtual group prior to election and each member of the virtual group is aware of participating in MIPS as a virtual group for an applicable performance period. Each member of the virtual group must retain a copy of the virtual group's written agreement. We note that the virtual group agreement is subject to the MIPS data validation and auditing requirements as described in section II.C.9.c. of this rule.
- Once an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during an applicable performance period one time prior to the start of an applicable submission period (§ 414.1315(c)(2)(iv)). We anticipate that virtual groups will use the Quality Payment Program Service Center as their designated CMS contact; however, we will define this further in subregulatory guidance.

For stage 2 of the election process, we would review all submitted election information; confirm whether or not each TIN within a virtual group is eligible to participate in MIPS as part of a virtual group; identify the NPIs within each TIN participating in a virtual group that are excluded from MIPS in order to ensure that such NPIs would not receive a MIPS payment adjustment or, when applicable and when information is available, would receive a payment adjustment based on a MIPS APM scoring standard; calculate the low-volume threshold at the individual and group levels in order to determine whether or not a solo practitioner or group is eligible to participate in MIPS as part of a virtual group; and notify virtual groups as to whether or not they are considered official virtual groups for the applicable performance period. For virtual groups that are determined to have met the virtual group formation criteria and identified as an official virtual group participating in MIPS for an applicable performance period, we would contact the official designated virtual group representative via email notifying the virtual group of its official virtual group status and issuing a virtual group identifier for performance (as described in section II.C.4.c. of this proposed rule) that would accompany the virtual group's submission of performance data during the submission period.

In regard to virtual group determinations pertaining to the low-volume threshold, we recognize that such determinations are made at the individual and group level, but not at the virtual group level. The low-volume threshold determinations are applicable to the way in which individual eligible clinicians and groups participate in MIPS as individual MIPS eligible clinicians (solo practitioners) or groups. For example, if an individual MIPS eligible clinician is part of a practice that is participating in MIPS at the individual level (reporting at the individual level), then the low-volume threshold determination is made at the individual level. Whereas, if an individual MIPS eligible clinician is part of a practice that is participating in MIPS at the group level (reporting at the group level), then the low-volume threshold determination at the group level would be applicable to such MIPS eligible clinician regardless of the low-volume threshold determination made at the individual level because such individual MIPS eligible clinician is part of a group reporting at the group level and the low-volume threshold determinations for groups applies to the group as a whole. Similarly, if a solo practitioner or a group with 10 or fewer eligible clinicians seeks to participate in MIPS at the virtual group level (reporting at the virtual group level), then the low-volume threshold determination at the individual or group level would be applicable to such solo practitioner or group with 10 or fewer eligible clinicians. Thus, solo practitioners (individual MIPS eligible clinicians) or groups with 10 or fewer eligible clinicians that are determined not to exceed the low-volume threshold at the individual or group level would not be eligible to participate in MIPS as an individual, group, or virtual group.

As we engaged in various discussions with stakeholders during the rulemaking process through listening sessions and user groups, stakeholders indicated that many solo practitioners and small groups have limited resources and technical capacities, which may make it difficult for the entities to form virtual groups without sufficient time and technical assistance. Depending on the resources and technical capacities of the entities, stakeholders conveyed that it may take entities 3 to 18 months to prepare to participate in MIPS as a virtual group. The majority of stakeholders indicated that virtual groups would need at least 6 to 12 months prior to the start of the 2018 performance period to form virtual groups, prepare health IT systems, and train staff to be ready for the implementation of virtual group related activities by January 1, 2018.

We recognize that for the first year of virtual group formation and implementation prior to the start of the 2018 performance period, the timeframe for virtual groups to make an election by registering would be relatively short, particularly from the date we issue the publication of a final rule toward the end of the 2017 calendar year. To provide solo practitioners and groups with 10 or fewer eligible clinicians with additional time to assemble and coordinate resources, and form a virtual group prior to the start of the 2018 performance period, we are providing virtual groups with an opportunity to make an election prior to the publication of our final rule. We intend for the virtual group election process to be available as early as mid-September of 2017; we will publicize the specific opening date via subregulatory guidance. Virtual groups would have from mid-September to December 1, 2017 to make an election for the 2018 performance year. In regard to our proposed policies pertaining to virtual group implementation (for example, definition of a virtual group and election process requirements), we intend to closely align with the statutory requirements in order to establish clear expectations for solo practitioners and

small groups, and have an opportunity to begin the preparation of forming virtual groups in advance of the publication of our final rule. However, any MIPS eligible clinicians applying to be a virtual group that does not meet all finalized virtual group requirements would not be permitted to participate in MIPS as a virtual group.

As previously noted, groups participating in a virtual group would have the size of their TIN determined for eligibility purposes. The virtual group size would be determined one time for each performance period. We recognize that the size of a group may fluctuate during a performance period with eligible clinicians and/or MIPS eligible clinicians joining or leaving a group. For groups within a virtual group that are determined to have a group size of 10 eligible clinicians or less based on the one time determination per applicable performance year, any new eligible clinicians or MIPS eligible clinicians that join the group during the performance period would participate in MIPS as part of the virtual group. In such cases, we recognize that a group may exceed 10 eligible clinicians associated with its TIN during an applicable performance period, but at the time of election, such group would have been determined eligible to form or join a virtual group given that the TIN did not have more than 10 eligible clinicians associated with its TIN. As previously noted, the virtual group representative would need to contact the Quality Payment Program Service Center to update the virtual group's information that was provided during the election period if any information changed during an applicable performance period one time prior to the start of an applicable submission period (for example, include new NPIs who joined a TIN that is part of a virtual group). Virtual groups must re-register before each performance period.

The statute provides that a solo practitioner (TIN/NPI) and a group with 10 or fewer eligible clinicians may elect to be in no more than one virtual group for a performance period. We note that such a solo practitioner or a group that is part of a virtual group may not elect to be in more than one virtual group for a performance period. Also, the statute determines that a virtual group election by the group for an applicable performance period applies to all MIPS eligible clinicians in the group. In the case of a TIN within a virtual group being acquired or merged with another TIN, or no longer operating as a TIN (for example, a group practice closes) during a performance period, such solo practitioner or group's performance data would continue to be attributed to the virtual group. The remaining members of a virtual group would continue to be part of the virtual group even if only one solo practitioner or group remains. We consider a TIN that is acquired or merged with another TIN, or no longer operating as a TIN (*e.g.,* a group practice closes) to mean a TIN that no longer exists or operates under the auspices of such TIN during a performance year.

As outlined in section 1848(q)(5)(I)(iii) of the Act and previously noted, a virtual group is a combination of TINs, which would include at least two separate TINs associated with a solo practitioner (TIN/NPI), or a group with 10 or fewer eligible clinicians and another such solo practitioner, or group. However, given that a virtual group must be a combination of TINs, we recognize that the composition of a virtual group could include, for example, one solo practitioner (NPI) who is practicing under multiple TINs, in which the solo practitioner would be able to form a virtual group with his or her own self based on each TIN assigned to the solo practitioner. For the number of TINs able to form a virtual group, we note that there is not a limit to the number of TINs able to comprise a virtual group.

f. Virtual Group Agreements

The statute provides for formal written agreements among the MIPS eligible clinicians electing to form a virtual group. We propose that each virtual group member would be required to execute formal written agreements with each other virtual group member to ensure that requirements and expectations of participation in MIPS are clearly articulated, understood, and agreed upon. We note that a virtual group may not include a solo practitioner or group as part of the virtual group unless an authorized person of the TIN has executed a formal written agreement. During the election process and submission of a virtual group election, a designated virtual group representative would be required to confirm through acknowledgement that an agreement is in place between each member of the virtual group. An agreement would be executed for at least one performance period. If a NPI joins or leaves a TIN, or a change is made to a TIN that impacts the agreement itself, such as a legal business name change, during the applicable performance year, a virtual group would be required to update the agreement to reflect such changes and submit changes to CMS via the Quality Payment Program Service Center.

We propose, at § 414.1315(c)(3), that a formal written agreement between each member of a virtual group must include the following elements:

- Expressly state the only parties to the agreement are the TINs and NPIs of the virtual group (at § 414.1315(c)(3)(i)). For example, the agreement may not be between a virtual group and another entity, such as an independent practice association (IPA) or management company that in turn has an agreement with one or more TINs within the virtual group. Similarly, virtual groups should not use existing contracts between TINs that include third parties.
- Be executed on behalf of the TINs and the NPIs by individuals who are authorized to bind the TINs and the NPIs, respectively at § 414.1315(c)(3)(ii)).
- Expressly require each member of the virtual group (including each NPI under each TIN) to agree to participate in MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws and regulations (including, but not limited to, federal criminal law, False Claims Act, anti-kickback statute, civil monetary penalties law, Health Insurance Portability and Accountability Act, and physician self-referral law) at § 414.1315(c)(3)(iii)).
- Require each TIN within a virtual group to notify all NPIs associated with the TIN of their participation in the MIPS as a virtual group at § 414.1315(c)(3)(iv)).
- Set forth the NPI's rights and obligations in, and representation by, the virtual group, including without limitation, the reporting requirements and how participation in MIPS as a virtual group affects the ability of the NPI to participate in the MIPS outside of the virtual group at § 414.1315(c)(3)(v)).
- Describe how the opportunity to receive payment adjustments will encourage each member of the virtual group (including each NPI under each TIN) to adhere to quality assurance and improvement at § 414.1315(c)(3)(vi)).
- Require each member of the virtual group to update its Medicare enrollment information, including the addition and deletion of NPIs billing through a TIN that is part of a virtual group, on a timely basis in accordance with Medicare program requirements and to notify the virtual group of any such changes within 30 days after the change at § 414.1315(c)(3)(vii)).
- Be for a term of at least one performance period as specified in the formal written agreement at § 414.1315(c)(3)(viii)).

• Require completion of a close-out process upon termination or expiration of the agreement that requires the TIN (group part of the virtual group) or NPI (solo practitioner part of the virtual group) to furnish all data necessary in order for the virtual group to aggregate its data across the virtual group at § 414.1315(c)(3)(ix)).

As part of the virtual group election ICR, we filed a 60-day notice on June 14, 2017 (82 FR 27257), which includes an agreement template that could be used by virtual groups and will be made available via subregulatory guidance. The agreement template is not required, but serves as a model agreement that could be utilized by virtual groups. The agreement template includes all necessary elements required for such an agreement.

We solicit public comment on these proposals.

Through the formal written agreements, we want to ensure that all members of a virtual group are aware of their participation in a virtual group. As noted above, formal written agreements must include a provision that requires each TIN within a virtual group to notify all NPIs associated with the TIN regarding their participation in the MIPS as a virtual group in order to ensure that each member of a virtual group is aware of their participation in the MIPS as a virtual group. We want to implement an approach that considers a balance between the need to ensure that all members of a virtual group are aware of their participation in a virtual group and the minimization of administration burden. We solicit public comment on approaches for virtual groups to ensure that all members of a virtual group are aware of their participation in the virtual group.

g. Reporting Requirements

As we noted in this proposed rule, we believe virtual groups should generally be treated under the MIPS as groups. Therefore, for MIPS eligible clinicians participating at the virtual group level, we propose the following requirements:

• Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level would have their performance assessed as a virtual group at § 414.1315(d)(1).

• Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level would need to meet the definition of a virtual group at all times during the performance period for the MIPS payment year (at § 414.1315(d)(2)).

• Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level must aggregate their performance data across multiple TINs in order for their performance to be assessed as a virtual group (at § 414.1315(d)(3)).

• MIPS eligible clinicians that elect to participate in MIPS at the virtual group level would have their performance assessed at the virtual group level across all four MIPS performance categories (at § 414.1315(d)(4)).

• Virtual groups would need to adhere to an election process established and required by CMS (at § 414.1315(d)(5)).

We solicit public comment on these proposals.

h. Assessment and Scoring for the MIPS Performance Categories

As noted above, section 1848(q)(5)(I)(i) of the Act provides that eligible clinicians electing to be a virtual group will: (1) Have their performance assessed for the quality and cost performance categories in a manner that applies the combined performance of all eligible clinicians in the virtual group to each MIPS eligible clinician (except for those participating in a MIPS APM or an Advanced APM under the MIPS APM scoring standard) in the virtual group for a performance period of a year; and (2) be scored based on the assessment of the combined performance described above regarding the quality and cost performance categories for a performance period. We believe it is critical for virtual groups to be assessed and scored at the virtual group level for all performance categories; it eliminates the burden of virtual group members having to report as a virtual group and separately outside of a virtual group. Additionally, we believe that the assessment and scoring at the virtual group level provides for a comprehensive measurement of performance, shared responsibility, and an opportunity to effectively and efficiently coordinate resources to also achieve performance under the improvement activities and the advancing care information performance categories. We propose at § 414.1315 that virtual groups would be assessed and scored across all four MIPS performance categories at the virtual group level for a performance period of a year.

In the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), we established the MIPS final score methodology, which will apply to virtual groups. We refer readers to sections II.C.7.b. and II.C.8. of this proposed rule for scoring policies that would apply to virtual groups.

As previously noted, we propose to allow solo practitioners and groups with 10 or fewer eligible clinicians that have elected to be part of a virtual group to have their performance measured and aggregated at the virtual group level across all four performance categories; however, we would apply payment adjustments at the individual TIN/NPI level. Each TIN/NPI would receive a final score based on the virtual group performance, but the payment adjustment would still be applied at the TIN/NPI level. We would assign the virtual group score to all TIN/NPIs billing under a TIN in the virtual group during the performance period.

During the performance year, we recognize that NPIs in a TIN that has joined a virtual group may also be participants in an APM. The TIN, as part of the virtual group, must submit performance data for all eligible clinicians associated with the TIN, including those participating in APMs, to ensure that all eligible clinicians associated with the TIN are being measured under MIPS.

For participants in MIPS APMs, we propose to use our authority under section 1115A(d)(1) for MIPS APM authorized under section 1115A of the Act, and under section 1899(f) for the Shared Savings Program, to waive the requirement under section 1848(q)(2)(5)(I)(i)(II) of the Act that requires performance category scores from virtual group reporting must be used to generate the composite score upon which the MIPS payment adjustment is based for all TIN/NPIs in the virtual group. Instead, we would use the score assigned to the MIPS eligible clinician based on the applicable APM Entity score to determine MIPS payment adjustments for all MIPS eligible clinicians that are part of an APM Entity participating in a MIPS APM, in accordance with § 414.1370, instead of determining MIPS payment adjustments for these MIPS eligible clinicians using the composite score of their virtual group.

APMs seek to deliver better care at lower cost and to test new ways of paying for care and measuring and assessing performance. In the CY 2017 Quality Payment Program final rule, we established policies to the address concerns we have expressed in regard to the application of certain MIPS policies to MIPS eligible clinicians in MIPS APMs (81 FR 77246 through 77269). In section II.C.6.g. of this proposed rule, we reiterate those concerns and propose additional policies for the APM scoring standard. We believe it is important to

consistently apply the APM scoring standard under MIPS for eligible clinicians participating in MIPS APMs in order to avoid potential misalignments between the evaluation of performance under the terms of the MIPS APM and evaluation of performance on measures and activities under MIPS, and to preserve the integrity of the initiatives we are testing. Therefore, we believe it is necessary to waive the requirement to only use the virtual group scores under section 1848(q)(5)(I)(i)(II) of the Act, and instead to apply the score under the APM scoring standard for eligible clinicians in virtual groups who are also in an APM Entity participating in an APM.

We note that MIPS eligible clinicians who are participants in both a virtual group and a MIPS APM would be assessed under MIPS as part of the virtual group and under the APM scoring standard as part of an APM Entity group, but would receive their payment adjustment based only on the APM Entity score. In the case of an eligible clinician participating in both a virtual group and an Advanced APM who has achieved QP status, the clinician would be assessed under MIPS as part of the virtual group, but would still be excluded from the MIPS payment adjustment as a result of his or her QP status. We refer readers to section II.C.6.g.(2) of this proposed rule for further discussion regarding the waiver and the CY 2017 Quality Payment Program final rule (81 FR 77013) for discussion regarding the timeframe used for determining QP status.

5. MIPS Performance Period

In the CY 2017 Quality Payment Program final rule (81 FR 77085), we finalized at § 414.1320(b)(1) that for purposes of the MIPS payment year 2020, the performance period for the quality and cost performance categories is CY 2018 (January 1, 2018 through December 31, 2018). For the improvement activities and advancing care information performance categories, we finalized at § 414.1320(b)(2) that for purposes of the MIPS payment year 2020, the performance period for the improvement activities and advancing care information performance categories is a minimum of a continuous 90-day period within CY 2018, up to and including the full CY 2018 (January 1, 2018, through December 31, 2018). We are not proposing any changes to these policies.

We also finalized at § 414.1325(f)(2) to use claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period for purposes of assessing performance and computing the MIPS payment adjustment. Lastly, we finalized that individual MIPS eligible clinicians or groups who report less than 12 months of data (due to family leave, etc.) would be required to report all performance data available from the applicable performance period (for example, CY 2018 or a minimum of a continuous 90-day period within CY 2018).

We are proposing at § 414.1320(c) and (c)(1) that for purposes of the MIPS payment year 2021 and future years, for the quality and cost performance categories, the performance period under MIPS would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable payment year. For example, for the MIPS payment year 2021, the performance period would be CY 2019 (January 1, 2019 through December 31, 2019), and for the MIPS payment year 2022 the performance period would be CY 2020 (January 1, 2020 through December 31, 2020).

We are proposing at § 414.1320(d) and (d)(1) that for purposes of the MIPS payment year 2021, the performance period for the improvement activities and advancing care information performance categories would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable payment year, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

We request comments on our proposals for the performance period for MIPS payment year 2021 and future years.

6. MIPS Performance Category Measures and Activities

a. Performance Category Measures and Reporting

(1) Submission Mechanisms

We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094) at § 414.1325(a) that individual MIPS eligible clinicians and groups must submit measures and activities, as applicable, for the quality, improvement activities, and advancing care information performance categories. For the cost performance category, we finalized that each individual MIPS eligible clinician's and group's cost performance would be calculated using administrative claims data. As a result, individual MIPS eligible clinicians and groups are not required to submit any additional information for the cost performance category. For individual eligible clinicians and groups that are not MIPS eligible clinicians, such as physical therapists, but elect to report to MIPS, we will calculate administrative claims-based cost measures and quality measures, if data are available. We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095) multiple data submission mechanisms for MIPS, which provide individual MIPS eligible clinicians and groups with the flexibility to submit their MIPS measures and activities in a manner that best accommodates the characteristics of their practice, as indicated in Tables 2 and 3. Table 2 summarizes the data submission mechanisms for individual MIPS eligible clinicians that we finalized at § 414.1325(b) and (e). Table 3 summarizes the data submission mechanisms for groups that are not reporting through an APM that we finalized at § 414.1325(c) and (e).

TABLE 2—DATA SUBMISSION MECHANISMS FOR MIPS ELIGIBLE CLINICIANS REPORTING INDIVIDUALLY

[TIN/NPI]

Performance category/submission combinations accepted	Individual reporting data submission mechanisms
Quality	Claims. QCDR. Qualified registry. EHR.
Cost	Administrative claims.[1]

TABLE 2—DATA SUBMISSION MECHANISMS FOR MIPS ELIGIBLE CLINICIANS REPORTING INDIVIDUALLY—Continued
[TIN/NPI]

Performance category/submission combinations accepted	Individual reporting data submission mechanisms
Advancing Care Information	Attestation. QCDR. Qualified registry. EHR.
Improvement Activities	Attestation. QCDR. Qualified registry. EHR.

TABLE 3—DATA SUBMISSION MECHANISMS FOR MIPS ELIGIBLE CLINICIANS REPORTING AS GROUPS (TIN)

Performance category/submission combinations accepted	Group reporting data submission mechanisms
Quality	QCDR. Qualified registry. EHR. CMS Web Interface (groups of 25 or more). CMS-approved survey vendor for CAHPS for MIPS (must be reported in conjunction with another data submission mechanism). and Administrative claims (for all-cause hospital readmission measure; no submission required).
Cost	Administrative claims.[1]
Advancing Care Information	Attestation. QCDR. Qualified registry. EHR. CMS Web Interface (groups of 25 or more).
Improvement Activities	Attestation. QCDR. Qualified registry. EHR. CMS Web Interface (groups of 25 or more).

We finalized at § 414.1325(d) that individual MIPS eligible clinicians and groups may elect to submit information via multiple mechanisms; however, they must use the same identifier for all performance categories, and they may only use one submission mechanism per performance category. In response to the CY 2017 Quality Payment Program final rule (81 FR 77089), we received comments supportive of the use of multiple submission mechanisms for a single performance category due to the flexibility it would provide clinicians. Another commenter supported such an approach because they believed that the scoring of only one submission mechanism per performance category may influence which quality measures a MIPS eligible clinician chooses to report given that the commenter believed only a limited number of measures relevant to one's practice might be available through a particular submission mechanism. The commenter also believed that such flexibility would encourage continued participation in MIPS.

We are proposing to revise § 414.1325(d) for purposes of the 2020 MIPS payment year and future years, beginning with performance periods occurring in 2018, to allow individual MIPS eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms for a single performance category (specifically, the quality, improvement activities, or advancing care information performance category). Under this proposal, individual MIPS eligible clinicians and groups that have fewer than the required number of measures and activities applicable and available under one submission mechanism could be required to submit data on additional measures and activities via one or more additional submission mechanisms, as necessary, provided that such measures and activities are applicable and available to them to receive the maximum number of points under a performance category. We considered an approach that would require MIPS eligible clinicians to first submit data on as many required measures and activities as possible via one submission mechanism before submitting data via an additional submission mechanism, but we believe that such an approach would limit flexibility.

If an individual MIPS eligible clinician or group submits the same measure through two different mechanisms, each submission would be calculated and scored separately. We do not have the ability to aggregate data on the same measure across submission mechanisms. We would only count the submission that gives the clinician the higher score, thereby avoiding the double count. We refer readers to section II.C.7. of this proposed rule, which further outlines how we propose to score measures and activities regardless of submission mechanism.

We believe that this flexible approach would help individual MIPS eligible clinicians and groups with reporting, as it provides more options for the submission of data for the applicable

[1] Requires no separate data submission to CMS: Measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. **NOTE:** Claims differ from administrative claims as they require MIPS eligible clinicians to append certain billing codes to denominator eligible claims to indicate the required quality action or exclusion occurred.

performance categories. For example, an individual MIPS eligible clinician or group submitting data on four applicable and available quality measures via EHR may not be able to receive the maximum number of points available under the quality performance category. However, with this proposed modification, the MIPS eligible clinician could meet the requirement to report six quality measures by submitting data on two additional quality measure via another submission mechanism, such as claims or qualified registry. This would enable the MIPS eligible clinician to receive the maximum number of points available under the quality performance category. We believe that by providing this flexibility, we would be allowing MIPS eligible clinicians the flexibility to choose the measures and activities that are most meaningful to them, regardless of the submission mechanism. We are aware that this proposal for increased flexibility in data submission mechanisms may increase complexity and in some instances additional costs for clinicians, as they may need to establish relationships with additional data submission mechanism vendors in order to report additional measures and/or activities for any given performance category. We would like to clarify that the requirements for the performance categories remain the same, regardless of the number of submission mechanisms used. It is also important to note for the improvement activities and advancing care information performance categories, that using multiple data submission mechanisms (for example, attestation and the qualified registry) may limit our ability to provide real-time feedback. While we strive to provide flexibility to individual MIPS eligible clinicians and groups, we would like to note that our goal within the MIPS program is to minimize complexity and administrative burden to individual MIPS eligible clinicians and groups. We request comments on this proposal.

As discussed in section II.C.4. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups. With respect to data submission mechanisms, we are proposing that virtual groups would be able to use a different submission mechanism for each performance category, and would be able to utilize multiple submission mechanisms for the quality performance category, beginning with performance periods occurring in 2018. However, virtual groups would be required to utilize the same submission mechanism for the improvement activities and the advancing care information performance categories.

For those MIPS eligible clinicians participating in a MIPS APM, who are on an APM Participant List on at least one of the three snapshot dates as finalized in the CY 2017 Quality Payment Program Final Rule (81 FR 77444 through 77445), or for MIPS eligible clinicians participating in a full TIN MIPS APM, who are on an APM Participant List on at least one of the four snapshot dates as discussed in section II.C.6.g.(2) of this proposed rule, the APM scoring standard applies. We refer readers to § 414.1370 and the CY 2017 Quality Payment Program final rule (81 FR 77246), which describes how MIPS eligible clinicians participating in APM entities submit data to MIPS in the form and manner required, including separate approaches to the quality and cost performance categories applicable to MIPS APMs. We are not proposing any changes to how APM entities in MIPS APMs and their participating MIPS eligible clinicians submit data to MIPS.

(2) Submission Deadlines

In the CY 2017 Quality Payment Program final rule (81 FR 77097), we finalized submission deadlines by which all associated data for all performance categories must be submitted for the submission mechanisms described in this rule.

As specified at § 414.1325(f)(1), the data submission deadline for the qualified registry, QCDR, EHR, and attestation submission mechanisms is March 31 following the close of the performance period. The submission period will begin prior to January 2 following the close of the performance period, if technically feasible. For example, for performance periods occurring in 2018, the data submission period will occur prior to January 2, 2019, if technically feasible, through March 31, 2019. If it is not technically feasible to allow the submission period to begin prior to January 2 following the close of the performance period, the submission period will occur from January 2 through March 31 following the close of the performance period. In any case, the final deadline will remain March 31, 2019.

At § 414.1325(f)(2), we specified that for the Medicare Part B claims submission mechanism, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. Lastly, for the CMS Web Interface submission mechanism, at § 414.1325(f)(3), we specified that the data must be submitted during an 8-week period following the close of the performance period that will begin no earlier than January 2, and end no later than March 31. For example, the CMS Web Interface submission period could span an 8-week timeframe beginning January 16 and ending March 13. The specific deadline during this timeframe will be published on the CMS Web site. We are not proposing any changes to the submission deadlines in this proposed rule.

b. Quality Performance Criteria

(1) Background

Sections 1848(q)(1)(A)(i) and (ii) of the Act require the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards and, using that methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act requires us to use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures and activities that must be specified under the quality performance category.

The statute does not specify the number of quality measures on which a MIPS eligible clinician must report, nor does it specify the amount or type of information that a MIPS eligible clinician must report on each quality measure. However, section 1848(q)(2)(C)(i) of the Act requires the Secretary, as feasible, to emphasize the application of outcomes-based measures.

Sections 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs, and section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage the use of CEHRT and QCDRs for reporting measures under the quality performance category under the final score methodology, but the statute does not limit the Secretary's discretion to establish other reporting mechanisms.

Section 1848(q)(2)(C)(iv) of the Act generally requires the Secretary to give consideration to the circumstances of non-patient facing MIPS eligible clinicians and allows the Secretary, to the extent feasible and appropriate, to apply alternative measures or activities to such clinicians.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77098 through 77099), we finalized MIPS quality criteria that focus on measures that are important to beneficiaries and maintain some of the

flexibility from PQRS, while addressing several of the comments we received in response to the CY 2017 Quality Payment Program proposed rule and the MIPS and APMs RFI.

- To encourage meaningful measurement, we finalized allowing individual MIPS eligible clinicians and groups the flexibility to determine the most meaningful measures and data submission mechanisms for their practice.
- To simplify the reporting criteria, we aligned the submission criteria for several of the data submission mechanisms.
- To reduce administrative burden and focus on measures that matter, we lowered the required number of the measures for several of the data submission mechanisms, yet still required that certain types of measures, particularly outcome measures, be reported.
- To create alignment with other payers and reduce burden on MIPS eligible clinicians, we incorporated measures that align with other national payers.
- To create a more comprehensive picture of a practice's performance, we also finalized the use of all-payer data where possible.

As beneficiary health is always our top priority, we finalized criteria to continue encouraging the reporting of certain measures such as outcome, appropriate use, patient safety, efficiency, care coordination, or patient experience measures. However, as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77098), we removed the requirement for measures to span across multiple domains of the NQS. We continue to believe the NQS domains are extremely important, and we encourage MIPS eligible clinicians to continue to strive to provide care that focuses on: Effective clinical care, communication and care coordination, efficiency and cost reduction, person and caregiver-centered experience and outcomes, community and population health, and patient safety. While we do not require that MIPS eligible clinicians select measures across multiple domains, we encourage them to do so. In addition, we believe the MIPS program overall, with the focus on the quality, cost, improvement activities, and advancing care information performance categories, will naturally cover many elements in the NQS.

(2) Contribution to Final Score

For MIPS payment year 2019, the quality performance category will account for 60 percent of the final score, subject to the Secretary's authority to assign different scoring weights under section 1848(q)(5)(F) of the Act. Section 1848(q)(2)(E)(i)(I)(aa) of the Act states that the quality performance category will account for 30 percent of the final score for MIPS. However, section 1848(q)(2)(E)(i)(I)(bb) of the Act stipulates that for the first and second years for which MIPS applies to payments, the percentage of the final score applicable for the quality performance category will be increased so that the total percentage points of the increase equals the total number of percentage points by which the percentage applied for the cost performance category is less than 30 percent. Section 1848(q)(2)(E)(i)(II)(bb) of the Act requires that, for the transition year for which MIPS applies to payments, not more than 10 percent of the final score shall be based on the cost performance category. Furthermore, section 1848(q)(2)(E)(i)(II)(bb) of the Act states that, for the second year for which MIPS applies to payments, not more than 15 percent of the final score shall be based on the cost performance category.

In the CY 2017 Quality Payment Program final rule (81 FR 77100), we finalized at § 414.1330(b) that, for MIPS payment years 2019 and 2020, 60 percent and 50 percent, respectively, of the MIPS final score will be based on the quality performance category. For the third and future years, 30 percent of the MIPS final score will be based on the quality performance category.

As discussed in section II.C.6.d. of this proposed rule, we are proposing to weight the cost performance category at zero percent for the second MIPS payment year (2020). In accordance with section 1848(q)(5)(E)(i)(I)(bb) of the Act, for the first 2 years, the percentage of the MIPS final score that would otherwise be based on the quality performance category (that is, 30 percent) must be increased by the same number of percentage points by which the percentage based on the cost performance category is less than 30 percent. Therefore, if our proposal to reweight the cost performance category for MIPS payment year 2020 is finalized, we would need to inversely reweight the quality performance category for the same year. Accordingly, we are proposing to modify § 414.1330(b)(2) to reweight the percentage of the MIPS final score based on the quality performance category for MIPS payment year 2020 as may be necessary to account for any reweighting of the cost performance category, if finalized. For example, if our proposal to reweight the cost performance category to zero percent for MIPS payment year 2020 is finalized, then we would modify § 414.1330(b)(2) to provide that performance in the quality performance category will comprise 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2020. We refer readers to section II.C.6.d. for more information on the cost performance category.

As also discussed in section II.C.6.d. of this proposed rule, we note that by reweighting the cost performance category to zero percent in performance period 2018, there will be a sharp increase in the cost performance category to a 30 percent weight in performance period 2019. In order to assist MIPS eligible clinicians and groups in obtaining additional comfort with measurement based on the cost performance category, we considered maintaining our previously-finalized cost performance category weight of 10 percent for the 2018 performance period. However, in our discussions with some MIPS eligible clinicians and clinician societies, eligible clinicians expressed their desire to down-weight the cost performance category to zero percent for an additional year with full knowledge that the cost performance category weight is set at 30 percent under the statute for the 2021 MIPS payment year. The clinicians we spoke with preferred our proposed approach and noted that they are actively preparing for full cost performance category implementation and would be prepared for the 30 percent statutory weight for the cost performance category for the 2021 MIPS payment year.

We intend to provide an initial opportunity for clinicians to review their performance based on the new episode-based measures at some point in the fall of 2017, as the measures are developed and as the information is available. We note that this feedback will be specific to the new episode-based measures that are developed under the process described above and may be presented in a different format than MIPS eligible clinicians' performance feedback as described in section II.C.9.a. of this proposed rule. However, our intention is to align the feedback as much as possible to ensure clinicians receive opportunities to review their performance on potential new episode-based measures for the cost performance category prior to the proposed 2019 MIPS performance period. We are unable to offer a list of new episode-based measures on which we will provide feedback because that will be determined in our ongoing development work described above. We are concerned that continuing to

provide feedback on the older episode-based measures along with feedback on new episode-based measures will be confusing and a poor use of resources. Because we are focusing on development of new episode-based measures, our feedback on episode-based measures that were previously developed will discontinue after 2017 as these measures would no longer be maintained or reflect changes in diagnostic and procedural coding. As described in section II.C.9.a. of this proposed rule, we intend to provide feedback on these new measures as they become available in a new format around summer 2018, in addition to the fall 2017 feedback discussed previously. We note that the feedback provided in the summer of 2018 will go to those MIPS eligible clinicians for whom we are able to calculate the episode-based measures, which means it would be possible that a clinical may not receive feedback on episode-based measures in both the fall of 2017 and the summer of 2018. We believe that receiving feedback on the new episode-based measures, along with the previously-finalized total per capita cost and MSPB measures, will support clinicians in their readiness for the proposed 2019 MIPS performance period.

Section 1848(q)(5)(B)(i) of the Act requires the Secretary to treat any MIPS eligible clinician who fails to report on a required measure or activity as achieving the lowest potential score applicable to the measure or activity. Specifically, under our finalized scoring policies, an individual MIPS eligible clinician or group that reports on all required measures and activities could potentially obtain the highest score possible within the performance category, assuming they perform well on the measures and activities they report. An individual MIPS eligible clinician or group who does not submit data on a required measure or activity would receive a zero score for the unreported items in the performance category (in accordance with section 1848(q)(5)(B)(i) of the Act). The individual MIPS eligible clinician or group could still obtain a relatively good score by performing very well on the remaining items, but a zero score would prevent the individual MIPS eligible clinician or group from obtaining the highest possible score within the performance category.

(3) Quality Data Submission Criteria

(a) Submission Criteria

(i) Submission Criteria for Quality Measures Excluding Groups Reporting via the CMS Web Interface and the CAHPS for MIPS Survey

In the CY 2017 Quality Payment Program final rule (81 FR 77114), we finalized at § 414.1335(a)(1) that individual MIPS eligible clinicians submitting data via claims and individual MIPS eligible clinicians and groups submitting data via all mechanisms (excluding the CMS Web Interface and the CAHPS for MIPS survey) are required to meet the following submission criteria. For the applicable period during the performance period, the individual MIPS eligible clinician or group will report at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, the individual MIPS eligible clinician or group will be required to report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. If fewer than six measures apply to the individual MIPS eligible clinician or group, then the individual MIPS eligible clinician or group would be required to report on each measure that is applicable. We defined ''applicable'' to mean measures relevant to a particular MIPS eligible clinician's services or care rendered. As discussed in section II.C.7.a.(2)(e)., we will only make determinations as to whether a sufficient number of measures are applicable for claims-based and registry submission mechanisms; we will not make this determination for EHR and QCDR submission mechanisms, for example.

Alternatively, the individual MIPS eligible clinician or group will report one specialty measure set, or the measure set defined at the subspecialty level, if applicable. If the measure set contains fewer than six measures, MIPS eligible clinicians will be required to report all available measures within the set. If the measure set contains six or more measures, MIPS eligible clinicians will be required to report at least six measures within the set. Regardless of the number of measures that are contained in the measure set, MIPS eligible clinicians reporting on a measure set will be required to report at least one outcome measure or, if no outcome measures are available in the measure set, the MIPS eligible clinician will report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) within the measure set in lieu of an outcome measure. MIPS eligible clinicians may choose to report measures in addition to those contained in the specialty measure set and will not be penalized for doing so, provided that such MIPS eligible clinicians follow all requirements discussed here.

In accordance with § 414.1335(a)(1)(ii), individual MIPS eligible clinicians and groups will select their measures from either the set of all MIPS measures listed or referenced in Table A of the Appendix in this proposed rule or one of the specialty measure sets listed in Table B of the Appendix in this proposed rule. We note that some specialty measure sets include measures grouped by subspecialty; in these cases, the measure set is defined at the subspecialty level. Previously finalized quality measures may be found in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816).

We also finalized the definition of a high priority measure at § 414.1305 to mean an outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure. Except as discussed in section II.C.6.b.(3)(a) of this proposed rule with regard to the CMS Web Interface and the CAHPS for MIPS survey, we are not proposing any changes to the submission criteria or definitions established for measures in this proposed rule.

In the CY 2017 Quality Payment Program final rule (81 FR 77114), we solicited comments regarding adding a requirement to our finalized policy that patient-facing MIPS eligible clinicians would be required to report at least one cross-cutting measure in addition to the high priority measure requirement for further consideration for the Quality Payment Program Year 2 and future years. For clarification, we consider a cross-cutting measure to be any measure that is broadly applicable across multiple clinical settings and individual MIPS eligible clinicians or groups within a variety of specialties. We specifically requested feedback on how we could construct a cross-cutting measure requirement that would be most meaningful to MIPS eligible clinicians from different specialties and that would have the greatest impact on improving the health of populations. We received conflicting feedback on adding a future requirement for MIPS eligible clinicians to report at least one cross-cutting measure in the Quality Payment Program Year 2 and future years.

Many commenters agreed that cross-cutting measures are applicable across multiple clinical settings and that MIPS eligible clinicians within a variety of specialties should report at least one cross-cutting measure. Some stated that cross-cutting measures promote shared accountability and improve the health of populations. Others recommended we continue to work with stakeholders and specialists, including solo and small practices, to develop cross-cutting measures for all settings, whether they be patient-facing or non-patient facing practices that are patient-centric (that is, following the patient and not the site of care) and recommended the term ''patient-centered measures'' rather than ''cross-cutting measures.'' In addition, some commenters stated we should consider measures that are multidisciplinary, foster cross-collaboration within virtual groups, improve patient outcomes, target high-cost areas, target areas with gaps in care, and include individual patient preferences in shared decision-making. A few commenters provided specific measures that they recommended utilizing as cross-cutting measures, such as: Screening for Hepatitis C; Controlling High Blood Pressure; Tobacco Use Cessation Counseling and Treatment; Advance Care Planning; or Medication Reconciliation. One commenter recommended we utilize shared accountability measures around surgical goals of care, shared decision making relying on some form of risk estimation such as a risk calculator, medication reconciliation, and a shared plan of care across clinicians. Another commenter suggested that instead of having a cross-cutting measure requirement, we could use health IT as a cross-cutting requirement. Specifically, the commenter noted we could require that at least one measure using end-to-end electronic reporting, or that at least one measure be tied to an improvement activity the clinician is performing. Other commenters suggested that we provide bonus points to practices that elect to submit data on cross-cutting measures and hold harmless from any future cross-cutting measure requirements MIPS eligible clinicians who have less than 15 instances in the measure denominator during the performance period, allow MIPS eligible clinicians to use high-priority measures in the place of a cross-cutting measure if necessary, and apply the guiding principles listed in NQF's ''Attribution: Principles and Approaches'' final report which may be found at *http://www.qualityforum.org/ProjectDescription.aspx?projectID=80808*.

Other commenters appreciated our decision not to finalize the requirement to report a cross-cutting measure in the transition year and requested that we not require cross-cutting measures in the future, as they believed it is administratively burdensome for clinicians and QCDRs and removes focus and resources from quality measures that are more relevant to MIPS eligible clinicians' scope of practice and important to their patients' treatment and outcomes. They stated that PQRS demonstrated the challenge of identifying cross-cutting measures that are truly meaningful across different specialties and that truly have an impact on improving the health of populations. Some stated we should focus on high-priority measures over cross-cutting measures. A few commenters did not agree that cross-cutting measures were relevant and stated they should not be a requirement in MIPS until all MIPS eligible clinicians can successfully meet the current requirements. Others did not agree that QCDRs should be required to submit cross-cutting measures because they believed that Congress did not intend for QCDRs to submit clinical process measures, that implementation may be complicated by practices that upgrade their health IT, and vendors have indicated it would take 12 to 18 months to implement system changes to support capture of cross-cutting measures. They also questioned the value of investing additional time and resources in this effort, especially if these cross-cutting measures are ultimately found to be topped out or removed. Others believed we should delay implementation until the Quality Payment Program Year 3 in order to allow MIPS eligible clinicians to focus on implementing new CEHRT requirements and modifying their processes to address lessons learned from reporting in the first 2 years.

Except as discussed in section II.C.6.b.(3)(a)(iii). of this proposed rule with regard to the CAHPS for MIPS survey, we are not proposing any changes to the submission criteria for quality measures in this proposed rule. We thank the commenters for their feedback and will take the comments into consideration in future rulemaking. We welcome additional feedback on meaningful ways to incorporate cross-cutting measurement into MIPS and the Quality Payment Program generally.

(ii) Submission Criteria for Quality Measures for Groups Reporting via the CMS Web Interface

In the CY 2017 Quality Payment Program final rule (81 FR 77116), we finalized at § 414.1335(a)(2) the following criteria for the submission of data on quality measures by registered groups of 25 or more eligible clinicians who want to report via the CMS Web Interface. For the applicable 12-month performance period, the group would be required to report on all measures included in the CMS Web Interface completely, accurately, and timely by populating data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module or measure. If the sample of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries. A group would be required to report on at least one measure for which there is Medicare patient data. Groups reporting via the CMS Web Interface are required to report on all of the measures in the set. Any measures not reported would be considered zero performance for that measure in our scoring algorithm. In addition, we are proposing to clarify that these criteria apply to groups of 25 or more eligible clinicians. Specifically, we propose to revise § 414.1335(a)(2)(i) to provide criteria applicable to groups of 25 or more eligible clinicians, report on all measures included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module.

In the CY 2017 Quality Payment Program final rule (81 FR 77116), we finalized to continue to align the 2019 CMS Web Interface beneficiary assignment methodology with the attribution methodology for two of the measures that were formerly in the VM: The population quality measure discussed in the CY 2017 Quality Payment Program proposed rule (81 FR 28188) and total per capita cost for all attributed beneficiaries discussed in the CY 2017 Quality Payment Program proposed rule (81 FR 28196). When establishing MIPS, we also finalized a modified attribution process to update the definition of primary care services and to adapt the attribution to different identifiers used in MIPS. These changes are discussed in the CY 2017 Quality Payment Program proposed rule (81 FR 28196). We note that groups reporting via the CMS Web Interface may also report the CAHPS for MIPS survey and receive bonus points for submitting that

measure. We are not proposing any changes to the submission criteria for quality measures for groups reporting via the CMS Web Interface in this proposed rule.

(iii) Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

In the CY 2017 Quality Payment Program final rule (81 FR 77100), we finalized at § 414.1335(a)(3) the following criteria for the submission of data on the CAHPS for MIPS survey by registered groups via CMS-approved survey vendor: For the applicable 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for a particular performance period to transmit survey measures data to CMS. The CAHPS for MIPS survey counts for one measure towards the MIPS quality performance category and, as a patient experience measure, also fulfills the requirement to report at least one high priority measure in the absence of an applicable outcome measure. In addition, groups that elect this data submission mechanism must select an additional group data submission mechanism (that is, qualified registries, QCDRs, EHR, etc.) in order to meet the data submission criteria for the MIPS quality performance category. The CAHPS for MIPS survey will count as one patient experience measure, and the group will be required to submit at least five other measures through one other data submission mechanism. A group may report any five measures within MIPS plus the CAHPS for MIPS survey to achieve the six measures threshold. We are not proposing any changes to the performance criteria for quality measures for groups electing to report the CAHPS for MIPS survey in this proposed rule.

In the CY 2017 Quality Payment Program final rule (see 81 FR 77120), we finalized retaining the CAHPS for MIPS survey administration period that was utilized for PQRS of November to February. However, this survey administration period has become operationally problematic for the administration of MIPS. In order to compute scoring, we must have the CAHPS for MIPS survey data earlier than the current survey administration period deadline allows. Therefore, we are proposing for the Quality Payment Program Year 2 and future years that the survey administration period would, at a minimum, span over 8 weeks and would end no later than February 28th following the applicable performance period. In addition, we propose to further specify the start and end timeframes of the survey administration period through our normal communication channels.

In addition, as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77116), we anticipated exploring the possibility of updating the CAHPS for MIPS survey under MIPS, specifically not finalizing all of the proposed Summary Survey Measures (SSMs). The CAHPS for MIPS survey currently consists of the core CAHPS Clinician & Group (CG–CAHPS) Survey developed by the Agency for Healthcare Research and Quality (AHRQ), plus additional survey questions to meet CMS's program needs. We are proposing for the Quality Payment Program Year 2 and future years to remove two SSMs, specifically, ''Helping You to Take Medication as Directed'' and ''Between Visit Communication'' from the CAHPS for MIPS survey. We are proposing to remove the SSM entitled ''Helping You to Take Medication as Directed'' due to low reliability. In 2014 and 2015, the majority of groups had very low reliability on this SSM. Furthermore, based on analyses conducted of SSMs in an attempt to improve their reliability, removing questions from this SSM did not result in any improvements in reliability. The SSM, ''Helping You to Take Medication as Directed,'' has also never been a scored measure with the Medicare Shared Savings Program CAHPS for Accountable Care Organizations (ACOs) Survey. We refer readers to the CY 2014 Physician Fee Schedule final rule for a discussion on the CAHPS for ACO survey scoring (79 FR 67909 through 67910) and measure tables (79 FR 67916 through 67917). The SSM entitled ''Between Visit Communication'' currently contains only one question. This question could also be considered related to other SSMs entitled: ''Care Coordination'' or ''Courteous and Helpful Office Staff,'' but does not directly overlap with any of the questions under that SSM. However, we are proposing to remove this SSM in order to maintain consistency with the Medicare Shared Savings Program which, utilizes the CAHPS for Accountable Care Organizations (ACOs) Survey. The SSM entitled ''Between Visit Communication'' has never been a scored measure with the Medicare Shared Savings Program CAHPS for ACOs Survey.

In addition to public comments we receive, we will also take into consideration analysis we will be conducting before finalizing this proposal. Specifically, we will review the findings of the CAHPS for ACO survey pilot, which was administered from November 2016 through February 2017. The CAHPS for ACO survey pilot utilized a survey instrument which did not contain the two SSMs we are proposing for removal from the CAHPS for MIPS survey. For more information on the other SSMs within the CAHPS for MIPS survey, please see the explanation of the CAHPS for PQRS survey in the CY 2016 PFS final rule with comment period (80 FR 71142 through 71143).

TABLE 4—PROPOSED SUMMARY SURVEY MEASURES (SSMS) INCLUDED IN THE CAHPS FOR MIPS SURVEY

Summary survey measures (SSMs)
Getting Timely Care, Appointments, and Information.
How Well Providers Communicate.
Patient's Rating of Provider.
Access to Specialists.
Health Promotion and Education.
Shared Decision-Making.
Health Status and Functional Status.
Courteous and Helpful Office Staff.
Care Coordination.
Stewardship of Patient Resources.

We are seeking comment on expanding the patient experience data available for the CAHPS for MIPS survey. Currently, the CAHPS for MIPS survey is available for groups to report under the MIPS. The patient experience survey data that is available on Physician Compare is highly valued by patients and their caregivers as they evaluate their health care options. However, in user testing with patients and caregivers in regard to the Physician Compare Web site, the users regularly ask for more information from patients like them in their own words. Patients regularly request that we include narrative reviews of individual clinicians and groups on the Web site. AHRQ is fielding a beta version of the CAHPS Patient Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*). This includes five open-ended questions designed to be added to the CG CAHPS survey, after which the CAHPS for MIPS survey is modeled. These five questions have been developed and tested in order to capture patient narratives in a scientifically grounded and rigorous way, setting it apart from other patient narratives collected by various health systems and patient rating sites. More scientifically rigorous patient narrative data would not only greatly benefit patients in their

decision for healthcare, but it would also greatly aid individual MIPS eligible clinicians and groups as they assess how their patients experience care. We are seeking comment on adding these five open-ended questions to the CAHPS for MIPS survey in future rulemaking. Beta testing is an ongoing process, and we anticipate reviewing the results of that testing in collaboration with AHRQ before proposing changes to the CAHPS for MIPS survey.

We are requiring, where possible, all-payer data for all reporting mechanisms, yet certain reporting mechanisms are limited to Medicare Part B data. Specifically, the CAHPS for MIPS survey currently relies on sampling protocols based on Medicare Part B billing; therefore, only Medicare Part B beneficiaries are sampled through that methodology. In the CY 2017 Quality Payment Program proposed rule (81 FR 28189), we requested comments on ways to modify the methodology to assign and sample patients for these mechanisms using data from other payers. We received mixed feedback on the use of all-payer data overall. The full discussion of the comments and the responses can be found in the CY 2017 Quality Payment Program final rule (81 FR 77123 through 77125). We are requesting additional comments on ways to modify the methodology to assign and sample patients using data from other payers for reporting mechanisms that are currently limited to Medicare Part B data. In particular, we are seeking comment on the ability of groups to provide information on the patients to whom they provide care during a calendar year, whether it would be possible to identify a list of patients seen by individual clinicians in the group, and what type of patient contact information groups would be able to provide. Further, we would like to seek comment on the challenges groups may anticipate in trying to provide this type of information, especially for vulnerable beneficiary populations, such as those lacking stable housing. We are also seeking comment on EHR vendors' ability to provide information on the patients who receive care from their client groups.

(b) Data Completeness Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77125), we finalized data completeness criteria for the transition year and MIPS payment year 2020. We finalized at § 414.1340 the data completeness criteria below for performance periods occurring in 2017.

- Individual MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR must report on at least 50 percent of the individual MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the performance period. In other words, for these submission mechanisms, we expect to receive quality data for both Medicare and non-Medicare patients. For the transition year, MIPS eligible clinicians whose measures fall below the data completeness threshold of 50 percent would receive 3 points for submitting the measure.
- Individual MIPS eligible clinicians submitting data on quality measures data using Medicare Part B claims, would report on at least 50 percent of the Medicare Part B patients seen during the performance period to which the measure applies. For the transition year, MIPS eligible clinicians whose measures fall below the data completeness threshold of 50 percent would receive 3 points for submitting the measure.
- Groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to report the CAHPS for MIPS survey must meet the data submission requirements on the sample of the Medicare Part B patients CMS provides.

In addition, we finalized an increased data completeness threshold of 60 percent for MIPS for performance periods occurring in 2018 for data submitted on quality measures using QCDRs, qualified registries, via EHR, or Medicare Part B claims. We noted that these thresholds for data submitted on quality measures using QCDRs, qualified registries, via EHR, or Medicare Part B claims would increase for performance periods occurring in 2019 and onward.

We are proposing to modify the previously established data completeness criteria for MIPS payment year 2020. Specifically, we would like to provide an additional year for individual MIPS eligible clinicians and groups to gain experience with MIPS before increasing the data completeness thresholds for data submitted on quality measures using QCDRs, qualified registries, via EHR, or Medicare Part B claims. We are concerned about the unintended consequences of accelerating the data completeness threshold so quickly, which may jeopardize MIPS eligible clinicians' ability to participate and perform well under the MIPS, particularly those clinicians who are least experienced with MIPS quality measure data submission. We want to ensure that an appropriate yet achievable level of data completeness is applied to all MIPS eligible clinicians. We continue to believe it is important to incorporate higher data completeness thresholds in future years to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures and to avoid any selection bias. Therefore, we propose, below, a 60 percent data completeness threshold for MIPS payment year 2021. We strongly encourage all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician's or group's overall performance for that measure. The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program. We are providing this notice to MIPS eligible clinicians so that they can take the necessary steps to prepare for higher data completeness thresholds in future years.

Therefore, we propose to revise the data completeness criteria for the quality performance category at § 414.1340(a)(2) to provide that MIPS eligible clinicians and groups submitting quality measures data using the QCDR, qualified registry, or EHR submission mechanism must submit data on at least 50 percent of the individual MIPS eligible clinician's or group's patients that meet the measure's denominator criteria, regardless of payer, for MIPS payment year 2020. We also propose to revise the data completeness criteria for the quality performance category at § 414.1340(b)(2) to provide that MIPS eligible clinicians and groups submitting quality measures data using Medicare Part B claims, must submit data on at least 50 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2020. We further propose at § 414.1340(a)(3), that MIPS eligible clinicians and groups submitting quality measures data using the QCDR, qualified registry, or EHR submission mechanism must submit data on at least 60 percent of the individual MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021. We also propose at § 414.1340(b)(3), that MIPS eligible clinicians and groups submitting quality measures data using Medicare Part B claims, must submit data on at least 60 percent of the applicable Medicare Part

B patients seen during the performance period to which the measure applies for MIPS payment year 2021. We would like to note that we anticipate for future MIPS payment years we will propose to increase the data completeness threshold for data submitted using QCDRs, qualified registries, EHR submission mechanisms, or Medicare Part B claims. As MIPS eligible clinicians gain experience with the MIPS, we would propose to steadily increase these thresholds for future years through rulemaking. In addition, we are seeking comment on what data completeness threshold should be established for future years.

In the CY 2017 Quality Payment Program final rule (81 FR 77125 through 77126), we finalized our approach of including all-payer data for the QCDR, qualified registry, and EHR submission mechanisms because we believed this approach provides a more complete picture of each MIPS eligible clinician's scope of practice and provides more access to data about specialties and subspecialties not currently captured in PQRS. In addition, those clinicians who utilize a QCDR, qualified registry, or EHR submission must contain a minimum of one quality measure for at least one Medicare patient. We are not proposing any changes to these policies in this proposed rule. As noted in the CY 2017 Quality Payment Program final rule, those MIPS eligible clinicians who fall below the data completeness thresholds will receive 3 points for the specific measures that fall below the data completeness threshold in the transition year of MIPS only. For the Quality Payment Program Year 2, we are proposing that MIPS eligible clinicians would receive 1 point for measures that fall below the data completeness threshold, with an exception for small practices of 15 or fewer who would still receive 3 points for measures that fail data completeness. We refer readers to section II.C.6.b.(3)(b) of this proposed rule for our proposed policies on instances when MIPS eligible clinicians' measures fall below the data completeness threshold.

(c) Summary of Data Submission Criteria

Table 5 reflects our proposed quality data submission criteria for MIPS payment year 2020 via Medicare Part B claims, QCDR, qualified registry, EHR, CMS Web Interface, and the CAHPS for MIPS survey. It is important to note that while we finalized at § 414.1325(d) in the CY 2017 Quality Payment Program final rule that individual MIPS eligible clinicians and groups may only use one submission mechanism per performance category, in section II.C.6.a.(1) of this rule, we are proposing to revise § 414.1325(d) for purposes of the 2020 MIPS payment year and future years to allow individual MIPS eligible clinicians and groups to submit measures and activities, as applicable, via as many submission mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories. We refer readers to section II.C.6.a.(1) of this proposed rule for further discussion of this proposal.

TABLE 5—SUMMARY OF PROPOSED QUALITY DATA SUBMISSION CRITERIA FOR MIPS PAYMENT YEAR 2020 VIA PART B CLAIMS, QCDR, QUALIFIED REGISTRY, EHR, CMS WEB INTERFACE, AND THE CAHPS FOR MIPS SURVEY

Performance period	Clinician type	Submission mechanism	Submission criteria	Data completeness
Jan 1–Dec 31	Individual MIPS eligible clinicians.	Part B Claims	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Individual MIPS eligible clinicians would have to select their measures from either the set of all MIPS measures listed or referenced in Table A or one of the specialty measure sets listed in Table B of the Appendix in this proposed rule.	50 percent of individual MIPS eligible clinician's Medicare Part B patients for the performance period.
Jan 1–Dec 31	Individual MIPS eligible clinicians, groups or virtual groups.	QCDR, Qualified Registry, & EHR.	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Individual MIPS eligible clinicians, groups, or virtual groups would have to select their measures from either the set of all MIPS measures listed or referenced in Table A or one of the specialty measure sets listed in Table B of the Appendix in this proposed rule.	50 percent of individual MIPS eligible clinician's, group's, or virtual group's patients across all payers for the performance period.
Jan 1–Dec 31	Groups or virtual groups.	CMS Web Interface ...	Report on all measures included in the CMS Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's or virtual group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group or virtual group would report on 100 percent of assigned beneficiaries.	Sampling requirements for the group's or virtual group's Medicare Part B patients.

TABLE 5—SUMMARY OF PROPOSED QUALITY DATA SUBMISSION CRITERIA FOR MIPS PAYMENT YEAR 2020 VIA PART B CLAIMS, QCDR, QUALIFIED REGISTRY, EHR, CMS WEB INTERFACE, AND THE CAHPS FOR MIPS SURVEY—Continued

Performance period	Clinician type	Submission mechanism	Submission criteria	Data completeness
Jan 1–Dec 31	Groups or virtual groups.	CAHPS for MIPS Survey.	CMS-approved survey vendor would need to be paired with another reporting mechanism to ensure the minimum number of measures is reported. CAHPS for MIPS survey would fulfill the requirement for one patient experience measure towards the MIPS quality data submission criteria. CAHPS for MIPS survey would only count for one measure under the quality performance category.	Sampling requirements for the group's or virtual group's Medicare Part B patients.

As discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups.

(4) Application of Quality Measures to Non-Patient Facing MIPS Eligible Clinicians

In the CY 2017 Quality Payment Program final rule (81 FR 77127), we finalized at § 414.1335 that non-patient facing MIPS eligible clinicians would be required to meet the applicable submission criteria that apply for all MIPS eligible clinicians for the quality performance category. We are not proposing any changes to this policy in this proposed rule.

(5) Application of Facility-Based Measures

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures used for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. We refer readers to section II.C.7.a.(4) of this proposed rule for a full discussion of our proposals regarding the application of facility-based measures.

(6) Global and Population-Based Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136), we did not finalize all of our proposals on global and population-based measures as part of the quality score. Specifically, we did not finalize our proposal to use the acute and chronic composite measures of the AHRQ Prevention Quality Indicators (PQIs). We agreed with commenters that additional enhancements, including the addition of risk adjustment, needed to be made to these measures prior to inclusion in MIPS. We did, however, calculate these measures at the TIN level, through the QRURs released in September 2016, and this data can be used by MIPS eligible clinicians for informational purposes.

We did finalize the all-cause hospital readmissions (ACR) measure from the VM Program as part of the quality measure domain for the MIPS total performance score. We finalized this measure with the following modifications. We did not apply the ACR measure to solo practices or small groups (groups of 15 or less). We did apply the ACR measure to groups of 16 or more who meet the case volume of 200 cases. A group was scored on the ACR measure even if it did not submit any quality measures, if it submitted in other performance categories. Otherwise, the group was not scored on the readmission measure if it did not submit data in any of the performance categories. In our transition year policies, the readmission measure alone would not produce a neutral to positive MIPS payment adjustment since in order to achieve a neutral to positive MIPS payment adjustment, an individual MIPS eligible clinician or group must submit information on one of the three performance categories as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77329). In addition, the ACR measure in the MIPS transition year CY 2017 was based on the performance period (January 1, 2017 through December 31, 2017). However, for MIPS eligible clinicians who did not meet the minimum case requirements, the ACR measure was not applicable. We are not proposing any changes for the global and population-based measures in this proposed rule. As discussed in section II.C.4.d. of this rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups.

c. Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment

(1) Background and Policies for the Call for Measures and Measure Selection Process

Under section 1848(q)(2)(D)(i) of the Act, the Secretary, through notice and comment rulemaking, must establish an annual list of MIPS quality measures from which MIPS eligible clinicians may choose for purposes of assessment for a performance period. The annual list of MIPS quality measures must be published in the **Federal Register** no later than November 1 of the year prior to the first day of a performance period. Updates to the annual list of MIPS quality measures must be published in the **Federal Register** no later than November 1 of the year prior to the first day of each subsequent performance period. Updates may include the addition of new MIPS quality measures, substantive changes to MIPS quality measures, and removal of MIPS quality measures. MIPS eligible clinicians reporting on the quality performance category are required to use the most recent version of the clinical quality measure (CQM) electronic specifications as indicated in the CY 2017 Quality Payment Program final rule (81 FR 77291). For purposes of the 2018 MIPS performance period, the spring 2017 version of the eCQM annual update to the measure specifications and any applicable addenda are available on the electronic clinical quality improvement (eCQI) Resource Center Web site at *https://ecqi.healthit.gov*. The CMS Quality Measure Development Plan (MDP) serves as a strategic framework for the future of the clinician quality measure development to support MIPS and APMs. The MDP is available on the CMS Web site and highlights known measurement gaps and recommends

approaches to close those gaps through development, use, and refinement of quality measures that address significant variation in performance gaps. We encourage stakeholders to develop additional quality measures for MIPS that would address the gaps.

Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards. However, we do not believe there needs to be any special restrictions on the type or make-up of the organizations that submit measures for consideration through the call for measures. Any such restriction would limit the type of quality measures and the scope and utility of the quality measures that may be considered for inclusion under the MIPS.

As we described previously in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*).

Submission of potential quality measures, regardless of whether they were previously published in a proposed rule or endorsed by an entity with a contract under section 1890(a) of the Act, which is currently the National Quality Forum, is encouraged. The annual Call for Measures process allows eligible clinician organizations and other relevant stakeholder organizations to identify and submit quality measures for consideration. Presumably, stakeholders would not submit measures for consideration unless they believe that the measure is applicable to clinicians and can be reliably and validly measured at the individual clinician level. The NQF-convened Measure Application Partnership (MAP) provides an additional opportunity for stakeholders to provide input on whether or not they believe the measures are applicable to clinicians as well as feasible, scientifically acceptable, and reliable and valid at the clinician level. Furthermore, we must go through notice and comment rulemaking to establish the annual list of quality measures, which gives stakeholders an additional opportunity to review the measures and provide input on whether or not they believe the measures are applicable to clinicians, as well as feasible, scientifically acceptable, and reliable and valid at the clinician level. Additionally, we are required by statute to submit new measures to an applicable specialty-appropriate, peer-reviewed journal.

As previously noted, we encourage the submission of potential quality measures regardless of whether such measures were previously published in a proposed rule or endorsed by an entity with a contract under section 1890(a) of the Act. However, we propose to request that stakeholders apply the following considerations when submitting quality measures for possible inclusion in MIPS:

- Measures that are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development and have started testing, at a minimum, with strong encouragement and preference for measures that complete or are near completion of reliability and validity testing.
- Measures that include a data submission method beyond claims-based data submission.
- Measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance.

We will apply these considerations when considering quality measures for possible inclusion in MIPS.

In addition, we note that we are likely to reject measures that do not provide substantial evidence of variation in performance; for example, if a measure developer submits data showing a small variation in performance among a group already composed of high performers, such evidence would not be substantial enough to assure us that sufficient variation in performance exists. We also note that we are likely to reject measures that are not outcome-based measures, unless (1) there is substantial documented and peer reviewed evidence that the clinical process measured varies directly with the outcome of interest and (2) it is not possible to measure the outcome of interest in a reasonable timeframe.

We also note that retired measures that were in one of CMS's previous quality programs, such as the Physician Quality Reporting System (PQRS) program, will likely be rejected if proposed for inclusion. This includes measures that were retired due to being topped out, as defined below. For example, measures may be retired due to attaining topped out status because of high performance, or measures that are retired due to a change in the evidence supporting their use.

In the CY 2017 Quality Payment Program final rule (81 FR 77153), we established that we will categorize measures into the six NQS domains (patient safety, person- and caregiver-centered experience and outcomes, communication and care coordination, effective clinical care, community/population health, and efficiency and cost reduction). We intend to submit future MIPS quality measures to the NQF-convened Measure Application Partnership's (MAP), as appropriate, and we intend to consider the MAP's recommendations as part of the comprehensive assessment of each measure considered for inclusion under MIPS.

In the CY 2017 Quality Payment Program final rule (81 FR 77155), we established that we use the Call for Quality Measures process as a forum to gather the information necessary to draft the journal articles for submission from measure developers, measure owners and measure stewards since we do not always develop measures for the quality programs. The submission of this information does not preclude us from conducting our own research using Medicare claims data, Medicare survey results, and other data sources that we possess. We submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals before including such measures in the final annual list of quality measures.

In the CY 2017 Quality Payment Program final rule (81 FR 77158), we established at § 414.1330(a)(2) that for purposes of assessing performance of MIPS eligible clinicians on the quality performance category, we use quality measures developed by QCDRs. In the circumstances where a QCDR wants to

use a QCDR measure for inclusion in the MIPS program for reporting, those measures go through a CMS approval process during the QCDR self-nomination period. We also established that we post the quality measures for use by QCDRs by no later than January 1 for performance periods occurring in 2018 and future years.

Previously finalized MIPS quality measures can be found in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675). Updates may include the proposal to add new MIPS quality measures, including measures selected 2 years ago during the Call for Measures process. The new MIPS quality measures proposed for inclusion in MIPS for the 2018 performance period and future years are found in Table A. The proposed new and modified MIPS specialty sets for the 2018 performance period and future years are listed in Table B, and include existing measures that are proposed with modifications, new measures, and measures finalized in the CY 2017 Quality Payment Program final rule. We note that the modifications made to the specialty sets may include the removal of certain quality measures that were previously finalized. The specialty measure sets should be used as a guide for eligible clinicians to choose measures applicable to their specialty. To clarify, some of the MIPS specialty sets have further defined subspecialty sets, each of which is effectively a separate specialty set. In instances where an individual MIPS eligible clinician or group reports on a specialty or subspecialty set, if the set has less than six measures, that is all the clinician is required to report. MIPS eligible clinicians are not required to report on the specialty measure sets, but they are suggested measures for specific specialties. Throughout measure utilization, measure maintenance should be a continuous process done by the measure owners, to include environmental scans of scientific literature about the measure. New information gathered during this ongoing review may trigger an ad hoc review. The specialty measure sets in Table B of the Appendix, include existing measures that are proposed with modifications, new measures, and measures that were previously finalized in the CY 2017 Quality Payment Program final rule. Please note that these specialty specific measure sets are not all inclusive of every specialty or subspecialty. On January 25, 2017, we announced that we would be accepting recommendations for potential new specialty measure sets for year 2 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2017 Quality Payment Program final rule, and include recommendations to add or remove the current MIPS quality measures from the specialty measure sets. The current specialty measure sets can be found on the Quality Payment Program Web site at *https://qpp.cms.gov/measures/quality*. All specialty measure sets submitted for consideration were assessed to ensure that they met the needs of the Quality Payment Program.

As a result, we propose to add new quality measures to MIPS (Table A), revise the specialty measure sets in MIPS (Table B), remove specific MIPS quality measures only from specialty sets (Table C.1), and propose to remove specific MIPS quality measures from the MIPS program for the 2018 performance period (Table C.2). The aforementioned measure tables can be found in the Appendix of this proposed rule. In addition, we are proposing to also remove cross cutting measures from most of the specialty sets. Specialty groups and societies reported that cross cutting measures may or may not be relevant to their practices, contingent on the eligible clinicians or groups. CMS chose to retain the cross cutting measures in Family Practice, Internal Medicine and Pediatrics specialty sets because they are frequently used in these practices. The proposed 2017 cross cutting measures, (81 FR 28447 through 28449), were compiled and placed in a separate table for eligible clinicians to elect to use or not, for reporting. To clarify, the cross-cutting measures are intended to provide clinicians with a list of measures that are broadly applicable to all clinicians regardless of the clinician's specialty. Even though it is not required to report on cross-cutting measures, it is provided as a reference to clinicians who are looking for additional measures to report outside their specialty. We continue to consider cross-cutting measures to be an important part of our quality measure programs, and seek comment on ways to incorporate cross-cutting measures into MIPS in the future. The proposed Table of Cross-Cutting Measures can be found in Table D of the Appendix.

For MIPS quality measures that are undergoing substantive changes, we propose to identify measures including, but not limited to measures that have had measure specification, measure title, and domain changes. MIPS quality measures with proposed substantive changes can be found at Table E of the Appendix.

The measures that would be used for the APM scoring standard and our authority for waiving certain measure requirements are described in section II.C.6.g.(3)(b)(ii) and the measures that would be used to calculate a quality score for the APM scoring standard are proposed in Tables 14, 15, and 16.

We also seek comment for this rule, on whether there are any MIPS quality measures that commenters believe should be classified in a different NQS domain than what is being proposed, or that should be classified as a different measure type (for example, process vs. outcome) than what is being proposed in this rule.

(2) Topped Out Measures

As defined in the CY 2017 Quality Payment Program final rule at (81 FR 77136), a measure may be considered topped out if measure performance is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made. Topped out measures could have a disproportionate impact on the scores for certain MIPS eligible clinicians, and provide little room for improvement for the majority of MIPS eligible clinicians. We refer readers to section II.C.7.a.(2)(c) of this proposed rule for additional information regarding the scoring of topped out measures.

We noted in the CY 2017 Quality Payment Program final rule that we anticipate removing topped out measures over time and sought comment on what point in time we should remove topped out measures from MIPS (81 FR 77286). We received the following comments.

Many commenters recommended that we retain topped out quality measures for 2 or more years because commenters believed they serve to motivate continued high-quality care; more clinicians may participate in MIPS compared to prior programs such as PQRS, and thus there may be more performance variation in MIPS showing that the measure is not actually topped out; declines in performance will not be captured if a measure is eliminated; it will help provide stability and encourage reporting in the early years of the MIPS program; removing topped out measures could further limit the number of measures available to specialists; and providing eligible clinicians and the public with information about high performance is as important as informing them about deficits.

A few commenters recommended that we publish information about topped out and potentially topped out measures prior to the performance period to allow clinicians time to adjust their reporting

strategies, with one commenter noting that improvement may be rewarded in addition to achievement. One commenter recommended pushing back the baseline performance period for the purpose of identifying topped out measures to 2018 because in the transition year it is unclear how many eligible clinicians will be reporting at different times and for what time period they will report.

Finally, a few commenters recommended that we consider specialty, case mix, and rural location before determining that a measure is topped out, specifically whether there is still room for improvement among certain specialist groups and to ensure that rural provider improvement is recognized. One commenter recommended that we determine topped out measures based on reporting in the Quality Payment Program rather than PQRS or value modifier reporting because the commenter believed using historical performance disadvantages small groups. A few commenters requested that the process for identifying and determining the removal of topped out measures be transparent, evidence-based, patient-centered, and include feedback from all appropriate stakeholders, including the medical community and measures owner. A few commenters specifically recommended that determining whether to remove a topped out measure be part of a rulemaking process while another commenter suggested that we seek out stakeholder input from the Measure Applications Partnership (MAP) on whether a measure should be removed, awarded lower points, or remain with benchmarks as a flat percentage.

We propose a 3-year timeline for identifying and proposing to remove topped out measures. After a measure has been identified as topped out for three consecutive years, we may propose to remove the measure through comment and rulemaking for the 4th year. Therefore, in the 4th year, if finalized through rulemaking, the measure would be removed and would no longer be available for reporting during the performance period. This proposal provides a path toward removing topped out measures over time, and will apply to the MIPS quality measures. QCDR measures that consistently are identified as topped out according to the same timeline as proposed below, would not be approved for use in year 4 during the QCDR self-nomination review process, and would not go through the comment and rulemaking process described below.

We propose to phase in this policy starting with a select set of six highly topped out measures identified in section II.C.7.a.(2)(c) of this proposed rule. In section II.C.7.a.(2)(c) of this proposed rule, we are also proposing to phase in special scoring for measures identified as topped out in the published benchmarks for two consecutive performance periods, starting with the select set of highly topped out measures for the 2018 MIPS performance period. An example illustrating the proposed timeline for the removal and special scoring of topped out measures, as it would be applied to the select set of highly topped out measures identified in section II.C.7.a.(2)(c), is as follows:

- *Year 1:* The measures are identified as topped out in the benchmarks published for the 2017 MIPS performance Period. The 2017 benchmarks are posted on the Quality Payment Program Web site: *https://qpp.cms.gov/resources/education*.
- *Year 2:* Measures are identified as topped out in the benchmarks published for the 2018 MIPS performance period. We refer readers to section II.C.7.a.(2)(c) of this proposed rule for additional information regarding the scoring of topped out measures.
- *Year 3:* Measures are identified as topped out in the benchmarks published for the 2019 MIPS performance period. The measures identified as topped out in the benchmarks published for the 2019 MIPS performance period and the previous two consecutive performance periods would continue to have special scoring applied for the 2019 MIPS performance period and would be considered, through notice-and-comment rulemaking, for removal for the 2020 MIPS performance period.
- *Year 4:* Topped out measures that are finalized for removal are no longer available for reporting. For example, the measures in the set of highly topped out measures identified as topped out for the 2017, 2018 and 2019 MIPS performance periods, and if subsequently finalized for removal will not be available on the list of measures for the 2020 MIPS performance period and future years.

For all other measures, the timeline would apply starting with the benchmarks for the 2018 MIPS performance period. Thus, the first year any other topped out measure could be proposed for removal would be in rulemaking for the 2021 MIPS performance period, based on the benchmarks being topped out in the 2018, 2019, and 2020 MIPS performance periods. If the measure benchmark is not topped out during one of the three MIPS performance periods, then the lifecycle would stop and start again at year 1 the next time the measure benchmark is topped out.

We seek comment on the above proposed timeline, specifically regarding the number of years before a topped out measure is identified and considered for removal, and under what circumstances we should remove topped out measures once they reach that point. For example, should we automatically remove topped out measures after they are identified for the proposed number of years or should we review measures identified for removal and consider certain criteria before removing the measure? If so what criteria should be considered? We would like to note that if for some reason a measure benchmark is topped out for only one submission mechanism benchmark, then we would remove that measure from the submission mechanism, but not remove the measure from other submission mechanisms available for submitting that measure.

We also seek comment on whether topped out Summary Survey Measures (SSMs), if topped out, should be considered for removal from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician or Group Survey measure due to high, unvarying performance within the SSM, or whether there is another alternative policy that could be applied for topped out SSMs within the CAHPS for MIPS Clinician or Group Survey measure.

In the CY 2017 Quality Payment Program final rule, we state that we do not believe it would be appropriate to remove topped out measures from the CMS Web Interface for the Quality Payment Program because the CMS Web Interface measures are used in MIPS and in APMs, such as the Shared Savings Program. Removing topped out measures from the CMS Web Interface would not be appropriate because we have aligned policies where possible, with the Shared Savings Program, such as using the Shared Savings Program benchmarks for the CMS Web Interface measures (81 FR 77285). In the CY 2017 Quality Payment Program final rule, we also finalized that MIPS eligible clinicians reporting via the CMS Web Interface must report all measures included in the CMS Web Interface (81 FR 77116). Thus, if a CMS Web Interface measure is topped out, the CMS Web Interface reporter cannot select other measures. We refer readers to section II.C.7.a.(2) of this proposed rule for information on scoring policies with regards to topped out measures from the CMS Web Interface for the Quality Payment Program. We are not proposing to include CMS Web Interface measures

in our proposal on removing topped out measures.

(3) Non-Outcome Measures

In the CY 2017 Quality Payment Program final rule, we sought comment on whether we should remove non-outcomes measures for which performance cannot reliably be scored against a benchmark (for example, measures that do not have 20 reporters with 20 cases that meet the data completeness standard) for 3 years in a row (81 FR 77288).

A few commenters recommended that measures that cannot be scored against a benchmark should be removed from the MIPS score. One commenter recommended that non-outcome measures that are unscorable should be given a weight of zero or re-weighted in the performance category. One commenter supported removing non-outcomes measures for which performance cannot reliably be scored against a benchmark for 3 years in a row. One commenter believed it would also be appropriate to remove outcomes measures under a separate more protracted timeline because the commenter believed the reporting of outcome measures is more difficult and expected to increase at a slower pace, while maintaining outcome measures would encourage the testing and availability of such measures.

Based on the need for CMS to further assess this issue, we are not proposing to remove non-outcome measures in this proposed rule. However, we seek comment on what the best timeline for removing both non-outcome and outcome measures that cannot be reliably scored against a benchmark for 3 years. We intend to revisit this issue and make proposals in future rulemaking.

(4) Quality Measures Determined To Be Outcome Measures

Under the MIPS, individual MIPS eligible clinicians are generally required to submit at least one outcome measure, or, if no outcome measure is available, one high priority measure. As such, our determinations as to whether a measure is an outcome measure is of importance to stakeholders. We utilize the following as a basis to determine if a measure is considered an outcome measure:

- Measure Steward and National Quality Forum (NQF) designation—For most measures, we will utilize the designation as determined by the measure steward and the measure's NQF designation to determine if it is an outcome measure or not. If this is not clear, we will consider the following step.
- Utilization of the CMS Blueprint definitions for outcome measures: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf*. An outcome of care is a health state of a patient resulting from health care. Outcome measures are supported by evidence that the measure has been used to detect the impact of one or more clinical interventions. Clinical analysts are utilized to evaluate the measure.

We also note that patient-reported outcome measures are considered outcome measures, as they measure the health of the patient directly resulting from the health care provided. Efficiency measures are not considered outcome measures, as they are measuring the cost of care associated with a specific level of care, but we do note that efficiency is considered a high priority measure.

After a MIPS quality measure is established in the program, it is generally only reviewed again if there are significant changes to a measure for the next program year that might warrant a change to the designation of outcome or not. In most cases, these updates are significant enough that they are usually presented as a new measure from the measure owner. New measures to the program will follow the criteria outlined above. QCDR measures however, are reviewed on a yearly basis (during the fall) regardless if there is a significant change or not. We refer readers to section II.C.10.a. for additional information on the QCDR self-nomination and measures review and approval process.

We seek comment on the criteria and process outlined above on how we designate outcome measures. Specifically are there additional criteria we should take into consideration when we determine if a measure meets the criteria of an outcome measure? Should we use different criteria for MIPS measures versus QCDR measures?

d. Cost Performance Category

(1) Background

(a) General Overview

Measuring cost is an integral part of measuring value as part of MIPS. In implementing the cost performance category for the transition year (2017 MIPS performance period/2019 MIPS payment year), we started with measures that had been used in previous programs but noted our intent to move towards episode-based measurement as soon as possible, consistent with the statute and the feedback from the clinician community. Specifically, we adopted 2 measures that had been used in the VM: The total per capita costs for all attributed beneficiaries measure (referred to as the total per capita cost measure) and the MSPB measure (81 FR 77166 through 77168). We also adopted 10 episode-based measures that had previously been included in the Supplemental Quality and Resource Use Reports (sQRURs) (81 FR 77171 through 77174).

At § 414.1325(e), we finalized that all measures used under the cost performance category would be derived from Medicare administrative claims data and, thus, participation would not require additional data submission. We finalized a reliability threshold of 0.4 for measures in the cost performance category (81 FR 77170). We also finalized a case minimum of 35 for the MSPB measure (81 FR 77171) and 20 for the total per capita cost measure (81 FR 77170) and each of the 10 episode-based measures (81 FR 77175) in the cost performance category to ensure the reliability threshold is met.

For the transition year, we finalized a policy to weight the cost performance category at zero percent in the final score in order to give clinicians more opportunity to understand the attribution and the scoring methodology and gain more familiarity with the measures through performance feedback (81 FR 77165 through 77166) so that clinicians may be able to act to improve their performance. In the CY 2017 Quality Payment Program final rule, we finalized a cost performance category weight of 10 percent for the 2020 MIPS payment year (81 FR 77165). For the 2021 MIPS payment year and beyond, the cost performance category will have a weight of 30 percent of the final score as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act.

For descriptions of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177).

As finalized at § 414.1370(g)(2), the cost performance category is weighted at zero percent for MIPS eligible clinicians scored under the MIPS APM scoring standard because many MIPS APM models incorporate cost measurement in other ways. For more on the APM scoring standard, see II.C.6.E. of this proposed rule.

(2) Weighting in the Final Score

We are proposing at § 414.1350(b)(2) to change the weight of the cost performance category from 10 percent to zero percent for the 2020 MIPS payment year. We continue to have concerns

about the level of familiarity and understanding of cost measures among clinicians. We will use this additional year in which the score in the cost performance category does not count towards the final score for outreach to increase understanding of the measures so that clinicians will be more comfortable with their role in reducing costs for their patients. In addition, we will use this additional year to develop more episode-based measures, which are cost measures that are focused on a clinical conditions or procedures. We intend to propose in future rulemaking to adopt episode-based measures currently in development.

Although we believe reducing this weight is appropriate given the level of understanding of the measures and the scoring standards, we note that section 1848(q)(5)(E)(i)(II)(aa) of the Act requires the cost performance category be assigned a weight of 30 percent of the MIPS final score beginning in the 2021 MIPS payment year. We recognize that assigning a zero percent weight to the cost performance category for the 2020 MIPS payment year may not provide a smooth enough transition for integrating cost measures into MIPS and may not provide enough encouragement to clinicians to review their performance on cost measures. This policy could reduce understanding of the measures when we reach the 2021 MIPS payment year and the cost performance category will be used to determine 30 percent of the final score for MIPS eligible clinicians, when in the two previous years it was weighted at zero. Therefore, we also seek comment on keeping the weight of the cost performance category at 10 percent for the 2020 MIPS payment year.

In our discussions with clinicians and clinician societies, clinicians expressed their desire to down-weight the cost performance category to zero percent for an additional year with full knowledge that the cost performance category weight is set at 30 percent under the statute for the 2021 MIPS payment year. The clinicians we spoke with preferred a low weighting and noted that they are actively preparing for cost performance category implementation and would be prepared for the 30 percent statutory weight for the cost performance category for the 2021 MIPS payment year. We intend to continue to provide education to clinicians to help them prepare for the upcoming 30 percent weight.

We invite public comments on this proposal of a zero percent weighting for the cost performance category and the alternative option of 10 percent weighting for the cost performance category for the 2020 MIPS payment year.

(3) Cost Criteria

(a) Measures Proposed for the MIPS Cost Performance Category

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. For the 2017 MIPS performance period, we will utilize 12 cost measures that are derived from Medicare administrative claims data. Two of these measures, the MSPB measure and total per capita cost measure, have been used in the VM (81 FR 77166 through 77168), and the remaining 10 are episode-based measures that were included in the sQRURs in 2014 and 2015 (81 FR 77171 through 77174).

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Section 1848(r) of the Act requires us to consider several factors when establishing these groups. For care episode groups, we must consider the patient's clinical problems at the time items and services are furnished during an episode of care, such as clinical conditions or diagnoses, whether inpatient hospitalization occurs, the principal procedures or services furnished, and other factors determined appropriate by the Secretary. For patient condition groups, we must consider the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period), and other factors determined appropriate.

Section 1848(r)(2) of the Act requires us to post on the CMS Web site a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post on the CMS Web site an operational list of such groups and codes. In December 2016, we published the Episode-Based Cost Measure Development for the Quality Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-Based-Cost-Measure-Development-for-the-Quality-Payment-Program.pdf*) and requested input on a draft list of care episode and patient condition groups and codes as required by section 1848(r)(2)(E) and (F) of the Act. We additionally requested feedback on our overall approach to cost measure development, including several pages of specific questions on the proposed approach for clinicians and stakeholders to provide feedback on. This feedback will be used to modify our cost measure development and ensure that our approach is continually informed by stakeholder feedback. We are currently reviewing the feedback that was recently received on that posting and will share plans to work with clinicians and others on the further developments of these episodes in the future.

We will be posting the operational list of care episode and patient condition groups in December 2017, as required by section 1848(r)(2)(G) of the Act. Section 1848(r)(2)(H) of the Act also requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate.

(ii) Total Per Capita Cost and MSPB Measures

For the 2018 MIPS performance period and future performance periods, we are proposing to include in the cost performance category the total per capita cost measure and the MSPB measure as finalized for the 2017 MIPS performance period. We refer readers to the description of these measures in the CY 2017 Quality Payment Program final rule (81 FR 77164 through 77171). We are proposing to include the total per capita cost measure because it is a global measure of all Medicare Part A and Part B costs during the performance period. MIPS eligible clinicians are familiar with the total per capita cost measure because the measure has been used in the VM since the 2015 payment adjustment period and performance feedback has been provided through the annual QRUR since 2013 (for a subset of groups that had 20 or more eligible professionals, based on 2014 performance) and to all groups in the annual QRUR since 2014 (based on 2013 performance) and mid-year QRUR since 2015. We are proposing to use the MSPB measure because many MIPS eligible

clinicians will be familiar with the measure from the VM, where it has been included since the 2016 payment adjustment period and in annual QRUR since 2014 (based on 2013 performance) and the mid-year QRUR since 2015, or its hospital-specified version, which has been a part of the Hospital VBP Program since 2015, based on 2013 performance. In addition to familiarity, these two measures cover a large number of patients and provide an important measurement of clinician contribution to the overall population that a clinician encounters.

We are not proposing any changes to the methodologies for payment standardization, risk adjustment, and specialty adjustment for these measures and refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77164 through 77171) for more information about these methodologies.

We will continue to evaluate cost measures that are included in MIPS on a regular basis and anticipate that measures could be added or removed, subject to rulemaking under applicable law, as measure development continues. We will also maintain the measures that are used in the cost performance category by updating specifications, risk adjustment, and attribution as appropriate. We anticipate including a list of cost measures for a given performance period in annual rulemaking.

We invite public comments on these proposals.

(iii) Episode-Based Measures

Episode-based measures differ from the total per capita cost measure and MSPB measure because their specifications only include services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given period of time. For the 2018 MIPS performance period, we are not proposing to include in the cost performance category the 10 episode-based measures that we adopted for the 2017 MIPS performance period in the CY 2017 Quality Payment Program final rule (81 FR 77171 through 77174). We instead will work to develop new episode-based measures, with significant clinician input, for future performance periods.

We received extensive comments on our proposal to include 41 of these episode-based measures for the 2017 MIPS performance period, which we responded to in the CY 2017 Quality Payment Program final rule (81 FR 77171 through 77174). We also received additional comments after publication of that final rule with comment period about the decision to include 10 episode-based measures for the 2017 MIPS performance period. Although comments were generally in favor of the inclusion of episode-based measures in the future, there was also overwhelming stakeholder interest in more clinician involvement in the development of these episode-based measures as required by section 1848(r)(2) of the Act. Although there was an opportunity for clinician involvement in the development of some of the episode-based measures included for the 2017 MIPS performance period, it was not as extensive as the process we are currently using to develop episode-based measures. We believe that the new episode-based measures, which we intend to propose in future rulemaking to include in the cost performance category for the 2019 MIPS performance period, will be substantially improved by more extensive stakeholder feedback and involvement in the process.

Thus far, stakeholder feedback has been sought in several ways. First, stakeholder feedback has been sought through various public postings. In October 2015 and April 2016, pursuant to section 1848(r)(2)(B) and (C) of the Act, we gathered input from stakeholders on the episode groups previously developed under section 1848(n)(9)(A) of the Act that has been used to inform the process of constructing the new episode-based cost measures. This feedback emphasized several key aspects of cost measure development such as attribution, risk adjustment, and alignment with quality measurement and patient outcomes. Stakeholders have also emphasized that feedback related to cost measures should be actionable and timely. In addition, a draft list of care episode and patient condition groups, along with trigger codes, was posted for comment in December 2016 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-Based-Cost-Measure-Development-for-the-Quality-Payment-Program.pdf*) as required by section 1848(r)(2)(E) of the Act and comments were accepted as required by section 1848(r)(2)(F) of the Act.

This draft list of care episode and patient condition groups and trigger codes was informed by engagement with clinicians from over 50 clinician specialty societies through a Clinical Committee formed to participate in cost measure development. The Clinical Committee work has provided input from a diverse array of clinicians on identifying conditions and procedures for episode groups. Moving forward, the Clinical Committee will recommend which services or claims would be counted in episode costs. This will ensure that cost measures in development are directly informed by a substantial number of clinicians and members of specialty societies.

In addition, a technical expert panel has met 3 times to provide oversight and guidance for our development of episode-based cost measures. The technical expert panel has offered recommendations for defining an episode group, assigning costs to the group, and attributing episode groups to clinicians. This expert feedback has been built into the current cost measure development process.

As this process continues, we are continuing to seek input from clinicians. Earlier this year, we opened an opportunity to submit the names of clinicians to participate in this process. This process remains open to additional individuals. We believe that episode-based measures will benefit from this comprehensive approach to development. In addition, because it is possible that the new episode-based measures under development could address similar conditions as those in the episode-based measures finalized for the 2017 MIPS performance period, we believe that it would be better to focus attention on the new episode-based measures, so that clinicians would not receive feedback or scores from two measures for the same patient condition or procedure. Recognizing that under section 1848(q)(5)(E)(i)(II)(aa) of the Act, we must assign a weight of 30 percent to the cost performance category for the 2021 MIPS payment year, we will endeavor to have as many episode-based measures available as possible for the proposed 2019 MIPS performance period.

We plan to include episode-based measures in the cost performance category in future years as they are developed and would propose new measures in future rulemaking.

Although we are not proposing to include any episode-based measures in calculating the cost performance category score for the 2020 MIPS payment year, we do plan to continue to provide confidential performance feedback to clinicians on their performance on episode-based measures developed under the processes required by section 1848(r)(2) of the Act as appropriate in order to increase familiarity with the concept of episode-based measurement as well as the specific episodes that could be included

in determining the cost performance category score in the future. Because these measures will be generated based on claims data like other cost measures, we will not collect any additional data from clinicians. As we develop new episode-based measures, we believe it is likely that they would cover similar clinical topics to those that are in the previously developed episode-based measures because of our intent to address common clinical conditions with episode-based measures. We aim to provide an initial opportunity for clinicians to review their performance based on the new episode-based measures at some point in the fall of 2017, as the measures are developed and as the information is available. We note that this feedback will be specific to the new episode-based measures that are developed under the process described above and may be presented in a different format than MIPS eligible clinicians' performance feedback as described in section II.C.9.a. of this proposed rule. However, our intention is to align the feedback as much as possible to ensure clinicians receive opportunities to review their performance on potential new episode-based measures for the cost performance category prior to the proposed 2019 MIPS performance period. We are unable to offer a list of new episode-based measures on which we will provide feedback because that will be determined in our ongoing development work described above. We are concerned that continuing to provide feedback on the older episode-based measures along with feedback on new episode-based measures will be confusing and a poor use of resources. Because we are focusing on development of new episode-based measures, our feedback on episode-based measures that were previously developed will discontinue after 2017 as these measures would no longer be maintained or reflect changes in diagnostic and procedural coding. As described in section II.C.9.a. of this proposed rule, we intend to provide feedback on these new measures as they become available in a new format around summer 2018. We note that the feedback provided in the summer of 2018 will go to those MIPS eligible clinicians for whom we are able to calculate the episode-based measures, which means it would be possible a clinician may not receive feedback on episode-based measures in both the fall of 2017 and the summer of 2018. We believe that receiving feedback on the new episode-based measures, along with the previously-finalized total per capita cost and MSPB measures, will support clinicians in their readiness for the proposed 2019 MIPS performance period.

As previously finalized in the CY 2017 Quality Payment Program final rule (81 FR 77173), the episode-based measures that we are not proposing for the 2018 MIPS performance period will be used for determining the cost performance category score for the 2019 MIPS payment year, although the cost performance category score will be weighted at zero percent in that year.

We invite public comments on this proposal.

(iv) Attribution

In the CY 2017 Quality Payment Program final rule, we changed the list of primary care services that had been used to determine attribution for the total per capita cost measure by adding transitional care management (CPT codes 99495 and 99496) codes and a chronic care management code (CPT code 99490) (81 FR 77169). In the CY 2017 Physician Fee Schedule final rule, we changed the payment status for two existing CPT codes (CPT codes 99487 and 99489) that could be used to describe care management from B (bundled) to A (active) meaning that the services would be paid under the Physician Fee Schedule (81 FR 80349). The services described by these codes are substantially similar to those described by the chronic care management code that we added to the list of primary care services beginning with the 2017 performance period. We therefore propose to add CPT codes 99487 and 99489, both describing complex chronic care management, to the list of primary care services used to attribute patients under the total per capita cost measure.

We are not proposing any changes to the attribution methods for the MSPB measure and refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169) for more information.

We invite public comment on our proposals.

(v) Reliability

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. Reliability is an important evaluation for cost measures to ensure that differences in performance are not the result of random variation. Statistically, reliability depends on performance variation for a measure across clinicians (''signal''), the random variation in performance for a measure within a clinician's attributed beneficiaries (''noise''), and the number of beneficiaries attributed to the clinician. High reliability for a measure suggests that comparisons of relative performance among clinicians are likely to be stable over different performance periods and that the performance of one clinician on the measure can be confidently distinguished from another. As an example of the statistical concept of reliability, a test in which the same individual received very different scores depending on how the included questions are framed would not be reliable. Potential reliability values range from 0.00 to 1.00, where 1.00 (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in differences in performance across clinicians, whereas 0.0 (lowest possible reliability) signifies that all variation could be a result of measurement error. The 0.4 reliability threshold that we adopted for the cost performance category measures in MIPS means that the majority of MIPS eligible clinicians and groups who meet the case minimum required for scoring under a measure have measure reliability scores that exceed 0.4. We generally consider reliability levels between 0.4 and 0.7 to indicate ''moderate'' reliability and levels above 0.7 to indicate ''high'' reliability.

We addressed comments we received on the CY 2017 Quality Payment Program proposed rule (81 FR 77169 through 77171), that expressed concern that our 0.4 reliability threshold was too low. Many commenters recommended that cost measures be included only when they could meet the standard of ''high'' reliability (0.7 or above). Many commenters on the CY 2017 Quality Payment Program final rule made similar comments. Commenters emphasized the importance of reliability; however, we have also seen commenters incorrectly refer to measures as being 40 percent reliable. Reliability is not a percentage but is instead a coefficient so a measure with 0.4 reliability does not reflect that it is only correct for 40 percent of those measured. We encourage a review of our analysis of reliability for the total per capita cost measure (80 FR 71282) and MSPB (81 FR 77169 through 77171).

Reliability is an important evaluation tool for an individual measure, but it is only one element of evaluation. Reliability generally increases as we increase the case size but a high reliability may also reflect low variation. A measure in which all clinicians perform at nearly the same rate would be reliable but not valuable in a program

that attempts to recognize and reward differential performance. A measure in which there is very little variation provides little value in a program like MIPS given the devotion of resources to developing and maintaining that measure over other potential measures. Reliability must also be considered in the context of a measurement system like MIPS which incorporates other elements of measurement. We understand and appreciate the concerns that have been expressed about reliability of measures. Medicine, however, always has a certain amount of variability which may affect the reliability score. We want strong reliability, but not at the expense of losing valuable information about clinicians. We are concerned that placing too much of an emphasis on reliability calculations could limit the applicability of cost measures to large group practices who, by nature of their size, have larger patient populations, thus depriving solo clinicians and individual reporters from being rewarded for efforts to better manage patients. Therefore, we are not proposing any adjustments to our reliability policies, but we will continue to evaluate reliability as we develop new measures and to ensure that our measures meet an appropriate standard.

(b) Attribution for Individuals and Groups

We are not proposing any changes for how we attribute cost measures to individual and group reporters. We refer readers to the CY 2017 Quality Payment Program final rule for more information (81 FR 77175 through 77176).

(c) Incorporation of Cost Measures With SES or Risk Adjustment

Both measures proposed for inclusion in the cost performance category for the 2018 MIPS performance period are risk adjusted at the measure level. Although the risk adjustment of the 2 measures is not identical, in both cases it is used to recognize the higher risk associated with demographic factors (such as age) or certain clinical conditions. We recognize that the risks accounted for with this adjustment are not the only potential attributes that could lead to a higher cost patient. Stakeholders have pointed to many other factors such as income level, race, and geography that they believe contribute to increased costs. These issues and our plans for attempting to address them are discussed in length in section II.C.7.b.(1)(a) of this rule.

(d) Incorporation of Cost Measures With ICD–10 Impacts

In section II.C.7.a.(1)(c) of this proposed rule, we discuss our proposal to assess performance on any measures impacted by ICD–10 updates based only on the first 9 months of the 12-month performance period. Because the total per capita cost and MSPB measures include costs from all Medicare Part A and B services, regardless of the specific ICD–10 codes that are used on claims, and do not assign patients based on ICD–10, we do not anticipate that any measures for the cost performance category would be affected by this ICD–10 issue during the 2018 MIPS performance period. However, as we continue our plans to expand cost measures to incorporate episode-based measures, ICD–10 changes could become important. Episode-based measures may be opened (triggered) by and may assign services based on ICD–10 codes. Therefore, a change to ICD–10 coding could have a significant effect on an episode-based measure. Changes to ICD–10 codes will be incorporated into the measure specifications on a regular basis through the measure maintenance process.

(e) Application of Measures to Non-Patient Facing MIPS Eligible Clinicians

We are not proposing changes to the policy we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77176) that we will attribute cost measures to non-patient facing MIPS eligible clinicians who have sufficient case volume, in accordance with the attribution methodology.

Section 1848(q)(2)(C)(iv) of the Act requires the Secretary to consider the circumstances of professional types who typically furnish services without patient facing interaction (non-patient facing) when determining the application of measures and activities. In addition, this section allows the Secretary to apply alternative measures or activities to non-patient facing MIPS eligible clinicians that fulfill the goals of a performance category. Section 1848(q)(5)(F) of the Act allows the Secretary to re-weight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved.

We believe that non-patient facing clinicians are an integral part of the care team and that their services do contributed to the overall costs but at this time we believe it better to focus on the development of a comprehensive system of episode-based measures which focus on the role of patient-facing clinicians. Accordingly, for the 2018 MIPS performance period, we are not proposing alternative cost measures for non-patient facing MIPS eligible clinicians or groups. This means that non-patient facing MIPS eligible clinicians or groups are unlikely to be attributed any cost measures that are generally attributed to clinicians who have patient-facing encounters with patients. Therefore, we anticipate that, similar to MIPS eligible clinicians or groups that do not meet the required case minimums for any cost measures, many non-patient facing MIPS eligible clinicians may not have sufficient cost measures applicable and available to them and would not be scored on the cost performance category under MIPS. We continue to consider opportunities to develop alternative cost measures for non-patient facing clinicians and solicit comment on this topic to inform our future rulemaking.

(f) Facility-Based Measurement as it Relates to the Cost Performance Category

In section II.C.7.a.(4) of this proposed rule, we discuss our proposal to implement section 1848(q)(2)(C)(ii) of the Act by assessing clinicians who meet certain requirements and elect participation based on the performance of their associated hospital in the Hospital VBP Program. We refer readers to that section for full details on our proposals related to facility-based measurement, including the measures and how the measures are scored, for the cost performance category.

e. Improvement Activity Criteria

(1) Background

Section 1848(q)(2)(C)(v)(III) of the Act defines an improvement activity as an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to specify improvement activities under subcategories for the performance period, which must include at least the subcategories specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act, and in doing so to give consideration to the circumstances of small practices, and practices located in rural areas and geographic health professional shortage areas (HPSAs).

Section 1848(q)(2)(C)(iv) of the Act generally requires the Secretary to give consideration to the circumstances of

non-patient facing individual MIPS eligible clinicians or groups and allows the Secretary, to the extent feasible and appropriate, to apply alternative measures and activities to such individual MIPS eligible clinicians and groups.

Section 1848(q)(2)(C)(v) of the Act required the Secretary to use a request for information (RFI) to solicit recommendations from stakeholders to identify improvement activities and specify criteria for such improvement activities, and provides that the Secretary may contract with entities to assist in identifying activities, specifying criteria for the activities, and determining whether individual MIPS eligible clinicians or groups meet the criteria set. For a detailed discussion of the feedback received from the MIPS and APMs RFI, see the CY 2017 Quality Payment Program 2017 final rule (81 FR 77177).

We defined improvement activities at § 414.1305 as an activity that relevant MIPS eligible clinicians, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

In the CY 2017 Quality Payment Program final rule (81 FR 77199), we solicited comments on activities that would advance the usage of health IT to support improvement activities. We received several comments in support of the concept to include emerging certified health IT capabilities as part of the activities in the Improvement Activities Inventory and several commenters supported our assessment that using CEHRT can aid in improving clinical practices and help healthcare organizations achieve success on numerous improvement activities, as well as the continued integration of improvement activities and advancing clinical information. However, several commenters expressed concern about health IT-associated burdens and costs and recommended that we also continue to offer diverse activities that do not rely on emerging capabilities of certified health IT, as they are not universally available or may only be offered as high cost add-on capabilities. Some commenters also requested that we be less prescriptive in our requirements for the use of health IT.

In response to the comments, we will continue to focus on incentivizing the use of health IT, telehealth, and connection of patients to community-based services. The use of health IT is an important aspect of care delivery processes described in many of the proposed new improvement activities in Table F in the Appendix of this proposed rule, and in Table H: Finalized Improvement Activities Inventory that we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77817 through 77831). In that same final rule, we also finalized a policy to allow MIPS eligible clinicians to achieve a bonus in the advancing care information performance category when they use functions included in CEHRT to complete eligible activities from the Improvement Activities Inventory. Please refer to section II.C.6.f.(2)(d) of this proposed rule for details on how improvement activities using CEHRT relate to the objectives and measures of the advancing care information and improvement activities performance categories. We are not proposing any changes to these policies for incentivizing the use of health IT in this proposed rule; however, we will continue to consider including emerging certified health IT capabilities as part of activities within the Improvement Activities Inventory in future years.

In addition, as noted previously, we believe a key goal of the Quality Payment Program is to establish a program that allows for close alignment of the four performance categories. Although we are not proposing any specific new policies, we seek comment on how we might provide flexibility for MIPS eligible clinicians to effectively demonstrate improvement through health IT usage while also measuring such improvement. We welcome public comment on these considerations.

(2) Contribution to the Final Score

In the CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we finalized at § 414.1355 that the improvement activities performance category would account for 15 percent of the final score. We also finalized at § 414.1380(b)(3)(iv) criteria for recognition as a certified-patient centered medical home or comparable specialty practice. We are proposing to clarify the term ''certified'' patient-centered medical home finalized at § 414.1380(b)(3)(iv). It has come to our attention that the common terminology utilized in the general medical community for ''certified'' patient-centered medical home is ''recognized'' patient-centered medical home. Therefore, in order to provide clarity we are proposing that the term ''recognized'' be accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS. Specifically, we propose to revise § 414.1380(b)(3)(iv) to provide that a MIPS eligible clinician or group in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, receives full credit for performance on the improvement activities performance category. For purposes of § 414.1380 (b)(3)(iv), ''full credit'' means that the MIPS eligible clinician or group has met the highest potential category score of 40 points. A practice is certified or recognized as a patient-centered medical home if it meets any of the criteria specified under § 414.1380(b)(3)(iv).

In the CY 2017 Quality Payment Program final rule (81 FR 77198), we requested commenters' specific suggestions for additional activities or activities that may merit additional points beyond the ''high'' level. Several commenters urged us to increase the overall number of high-weighted activities in this performance category. Some commenters recommended additional criteria for designating high-weighted activities, such as an improvement activity's impact on population health, medication adherence, and shared decision-making tools, and encouraged us to be more transparent in our weighting decisions. Several commenters recommended that we weight registry-related activities as high, and suggested that we award individual MIPS eligible clinicians and groups in APMs full credit in this performance category. The commenters also offered many recommendations for changing current medium-weighted activities to high and offered many specific suggestions for new high-weighted improvement activities.

In response to the comments, we are proposing new, high-weighted activities in Table F in the Appendix of this proposed rule. As explained in the CY 2017 Quality Payment Program final rule (81 FR 77194), we believe that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being. We are not proposing changes to this approach in this proposed rule; however, we will take these suggested additional criteria into consideration for designating high-weighted activities in future rulemaking. For MIPS eligible clinicians participating in MIPS APMs, we finalized a policy to reduce reporting burden through the APM scoring standard for this category to recognize improvement activities work performed through participation in MIPS APMs. This policy is codified at § 414.1370(g)(3), and we refer readers to the CY 2017 Quality Payment Program

final rule for further details on reporting and scoring this category under the APM Scoring Standard (81 FR 77259 through 77260).

(3) Improvement Activities Data Submission Criteria

(a) Submission Mechanisms

In the CY 2017 Quality Payment Program final rule (81 FR 77180), we discussed that for the transition year of MIPS we would allow for submission of data for the improvement activities performance category using the qualified registry, EHR, QCDR, CMS Web Interface, and attestation data submission mechanisms through attestation. Specifically, we finalized a policy that regardless of the data submission method, with the exception of MIPS eligible clinicians in MIPS APMs, all individual MIPS eligible clinicians or groups must select activities from the Improvement Activities Inventory. In addition, we finalized at § 414.1360 that for the transition year of MIPS, all individual MIPS eligible clinicians or groups, or third party intermediaries such as health IT vendors, QCDRs and qualified registries that submit on behalf of an individual MIPS eligible clinician or group, must designate a ''yes'' response for activities on the Improvement Activities Inventory. In the case where an individual MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, the individual MIPS eligible clinician or group will certify all improvement activities were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf. We would like to maintain stability in the Quality Payment Program and continue this policy into future years. Therefore, we are proposing at § 414.1360 that for purposes of the transition year of MIPS and future years all individual MIPS eligible clinicians or groups, or third party intermediaries such as health IT vendors, QCDRs and qualified registries that submit on behalf of an individual MIPS eligible clinician or group, must designate a ''yes'' response for activities on the Improvement Activities Inventory. In the case where an individual MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, the MIPS eligible clinician or group will certify all improvement activities were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf. In addition, as discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups.

We would like to note that while we finalized at § 414.1325(d) in the CY 2017 Quality Payment Program final rule that individual MIPS eligible clinicians and groups may only use one submission mechanism per performance category, in section II.C.6.a.(1) of this proposed rule, we are proposing to revise § 414.1325(d) for purposes of the 2020 MIPS payment year and future years to allow individual MIPS eligible clinicians and groups to submit measures and activities, as applicable, via as many submission mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories. We refer readers to section II.C.6.a.(1) of this proposed rule for further discussion of this proposal.

We also included a designation column in the Improvement Activities Inventory at Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817) that indicated which activities qualified for the advancing care information bonus finalized at § 414.1380. In future updates to the Improvement Activities Inventory we intend to continue to indicate which activities qualify for the advancing care information performance category bonus.

In the CY 2017 Quality Payment Program final rule (81 FR 77181), we clarified that if one MIPS eligible clinician (NPI) in a group completed an improvement activity, the entire group (TIN) would receive credit for that activity. In addition, we specified that all MIPS eligible clinicians reporting as a group would receive the same score for the improvement activities performance category if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period. As discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups. We are not proposing any changes to this policy in this proposed rule. However, we are requesting comment on whether we should establish a minimum threshold (for example, 50 percent) of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (TIN) to receive credit in the improvement activities performance category in future years. In addition, we are requesting comments on recommended minimum threshold percentages and whether we should establish different thresholds based on the size of the group. For example, in considering different thresholds we could attribute recognition as a certified or recognized patient-centered medical home or comparable specialty practice at the individual TIN/NPI level, and attribute this designation to the group under which they bill if they are participating in MIPS as a group or as part of a virtual group. A group or virtual group consisting of 100 NPIs could have a reporting threshold of 50 percent while a group consisting of 10 NPIs could have a lower reporting threshold of 10 percent. We are concerned that while establishing any specific threshold for the percentage of NPIs in a TIN that must participate in an improvement activity for credit will incentivize some groups to move closer to the threshold, it may have the unintended consequence of incentivizing groups who are exceeding the threshold to gravitate back toward the threshold. Therefore, we are requesting comments on how to set this threshold while maintaining the goal of promoting greater participation in an improvement activity.

Additionally, we noted in the CY 2017 Quality Payment Program final rule (81 FR 77197) that we intended, in future years, to score the improvement activities performance category based on performance and improvement, rather than simple attestation. We seek comment on how we could measure performance and improvement; we are especially interested in ways to measure performance without imposing additional burden on eligible clinicians, such as by using data captured in eligible clinicians' daily work.

(b) Submission Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77185), we finalized at § 414.1380 to set the improvement activities submission criteria under MIPS, to achieve the highest potential score, at two high-weighted improvement activities or four medium-weighted improvement activities, or some combination of high and medium-weighted improvement activities. While the minimum reporting period for one improvement activity is 90 days, the maximum frequency with which an improvement activity may be reported would be once during the 12-month performance period. In addition, as discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups.

We established exceptions to the above for: small practices; practices located in rural areas; practices located in geographic HPSAs; non-patient facing

individual MIPS eligible clinicians or groups; and individual MIPS eligible clinicians and groups that participate in a MIPS APM or a patient-centered medical home submitting in MIPS. Specifically, for individual MIPS eligible clinicians and groups that are small practices, practices located in rural areas or geographic HPSAs, or non-patient facing individual MIPS eligible clinicians or groups, to achieve the highest score, one high-weighted or two medium-weighted improvement activities are required. For these individual MIPS eligible clinicians and groups, in order to achieve one-half of the highest score, one medium-weighted improvement activity is required.

Under the APM scoring standard, all clinicians identified on the Participation List of an APM receive at least one-half of the highest score applicable to the MIPS APM. To develop the improvement activities score assigned to each MIPS APM, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians. If by our assessment the MIPS APM does not receive the maximum improvement activities performance category score then the APM entity can submit additional improvement activities. All other individual MIPS eligible clinicians or groups that we identify as participating in APMs that are not MIPS APMs will need to select additional improvement activities to achieve the improvement activities highest score. We refer readers to section II.C.6.g. of this proposed rule for further discussion of the APM scoring standard.

We also provided full credit for the improvement activities performance category, as required by law, for an individual MIPS eligible clinician or group that has received certification or accreditation as a patient-centered medical home or comparable specialty practice from a national program or from a regional or state program, private payer or other body that administers patient-centered medical home accreditation and certifies 500 or more practices for patient-centered medical home accreditation or comparable specialty practice certification, or for an individual MIPS eligible clinician or group that is a participant in a medical home model.

We also noted in the CY 2017 Quality Payment Program final rule that practices may receive this designation at a practice level and that TINs may be comprised of both undesignated practices and designated practices (81 FR 77178). We finalized at § 414.1380(b)(3)(viii) that to receive full credit as a certified patient-centered medical home or comparable specialty practice, a TIN that is reporting must include at least one practice that is a certified patient-centered medical home or comparable specialty practice. We also indicated that we would continue to have more stringent requirements in future years, and would lay the groundwork for expansion towards continuous improvement over time (81 FR 77189). We received many comments on the CY 2017 Quality Payment Program final rule regarding our transition year policy that only one practice site within a TIN needs to be certified as a patient-centered medical home for the entire TIN to receive full credit in the improvement activities performance category. While several commenters supported our transition year policy, others disagreed and suggested to move to a more stringent requirement in future years while still offering some flexibility. Accordingly, we propose to revise § 414.1380(b)(3)(x) to provide that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice. This is an increase to the requirement that only one practice site within a TIN needs to be certified as a patient-centered medical home, but does not require every site be certified, which could be overly restrictive given that some sites within a TIN may be in the process of being certified as patient-centered medical homes. In addition, we believe a 50 percent threshold is achievable which is supported by a study of physician-owned primary care groups in a recent Annals of Family Medicine article (Casalino, et al., 2016) *http://www.annfammed.org/content/14/1/16.full*. For nearly all groups in this study (sampled with variation in size and geographic area) at least 50 percent of the practice sites within the group had a medical home designation. If the group is unable to meet the 50 percent threshold then the individual MIPS eligible clinician may choose to receive full credit as a certified patient-centered medical home or comparable specialty practice by reporting as an individual for all performance categories. In addition, as discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups. Further, we welcome suggestions on an appropriate threshold for the number of NPIs within the TIN that must be recognized as a certified patient-centered medical home or comparable specialty practice to receive full credit in the improvement activities performance category.

We have determined that the Comprehensive Primary Care Plus (CPC+) APM design satisfies the requirements to be designated as a medical home model, as defined in § 414.1305, and is therefore a certified or recognized patient-centered medical home for purposes of the improvement activities performance category. The CPC+ model meets the criteria to be an Advanced APM. CPC+ eligibility criteria for practices include, but are not limited to, the use of CEHRT and care delivery activities such as: Assigning patients to clinician panels; providing 24/7 clinician access; and supporting quality improvement activities. Control groups in CPC+ are required to meet the same eligibility criteria as those selected to be active participants in the model. For Round 2 of CPC+, CMS is randomly assigning accepted practices into the intervention group or a control group. Practices accepted into CPC+ and randomized into the control group have satisfied the requirements for participation in CPC+, a medical home model, and we believe that the MIPS eligible clinicians in the control group should therefore receive full credit for the improvement activities performance category. In addition, the practices randomized to the CPC+ control group must sign a Participation Agreement with us; the agreement will require practices in a control group to maintain a Practitioner Roster of all MIPS eligible clinicians in the practice.

Accordingly, we are proposing that MIPS eligible clinicians in practices that have been randomized to the control group in the CPC+ APM would receive full credit as a medical home model, and therefore a certified patient-centered medical home, for the improvement activities performance category. MIPS eligible clinicians who attest that they are in practices that have been randomized to the control group in the CPC+ APM would receive full credit for the improvement activities performance category for each performance period in which they are on the Practitioner Roster, the official list of eligible clinicians participating in a practice in the CPC+ control group. The inclusion of MIPS eligible clinicians in practices that have been randomized into the CPC+ control group recognizes that they have met the

requirements to receive full credit for performance in the improvement activities performance category as a medical home model, and will help ensure more equitable treatment of the CPC+ control group by allowing clinicians in the control group that have met the criteria for participation in the CPC+ APM to receive the same recognition as those actively participating in the CPC+ intervention group.

We request comments on these proposals.

(c) Required Period of Time for Performing an Activity

In the CY 2017 Quality Payment Program final rule (81 FR 77186), we specified at § 414.1360 that MIPS eligible clinicians or groups must perform improvement activities for at least 90 consecutive days during the performance period for improvement activities performance category credit. Activities, where applicable, may be continuing (that is, could have started prior to the performance period and are continuing) or be adopted in the performance period as long as an activity is being performed for at least 90 days during the performance period. In addition, as discussed in section II.C.4.d. of this proposed rule, we are proposing to generally apply our previously finalized and proposed group policies to virtual groups. We are not proposing any changes to the required period of time for performing an activity for the improvement activities performance category in this proposed rule.

(4) Application of Improvement Activities to Non-Patient Facing Individual MIPS Eligible Clinicians and Groups

In the CY 2017 Quality Payment Program final rule (81 FR 77187), we specified at § 414.1380(b)(3)(vii) that for non-patient facing individual MIPS eligible clinicians or groups, to achieve the highest score one high-weighted or two medium-weighted improvement activities are required. For these individual MIPS eligible clinicians and groups, in order to achieve one-half of the highest score, one medium-weighted improvement activity is required. We are not proposing any changes to the application of improvement activities to non-patient facing individual MIPS eligible clinicians and groups for the improvement activities performance category in this proposed rule.

(5) Special Consideration for Small, Rural, or Health Professional Shortage Areas Practices

In the CY 2017 Quality Payment Program final rule (81 FR 77188), we finalized at § 414.1380(b)(3)(vii) that one high-weighted or two medium-weighted improvement activities are required for individual MIPS eligible clinicians and groups that are small practices or located in rural areas, or geographic HPSAs, to achieve full credit. In addition, we specified at § 414.1305 that a rural area means ZIP codes designated as rural, using the most recent HRSA Area Health Resource File data set available. Lastly, we finalized the following definitions at § 414.1305: (1) Small practices is defined to mean practices consisting of 15 or fewer clinicians and solo practitioners; and (2) Health Professional Shortage Areas (HPSA) refers to areas as designated under section 332(a)(1)(A) of the Public Health Service Act. We are not proposing any changes to the special consideration for small, rural, or health professional shortage areas practices for the improvement activities performance category in this proposed rule.

(6) Improvement Activities Subcategories

In the CY 2017 Quality Payment Program final rule (81 FR 77190), we finalized at § 414.1365 that the improvement activities performance category will include the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. In addition, we finalized at § 414.1365 the following additional subcategories: Achieving Health Equity; Integrated Behavioral and Mental Health; and Emergency Preparedness and Response. We are not proposing any changes to the improvement activities subcategories for the improvement activities performance category in this proposed rule.

(7) Improvement Activities Inventory

(a) Proposed Approach on the Annual Call for Activities Process for Adding New Activities

In Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817), we finalized the Improvement Activities Inventory for MIPS. In addition, through subregulatory guidance we provided an informal process for submitting new improvement activities for potential inclusion in the comprehensive Improvement Activities Inventory for the Quality Payment Program Year 2. During this transition period we received input from various MIPS eligible clinicians and organizations suggesting possible new activities via a nomination form that was posted on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallForMeasures.html*. We are proposing new activities and changes to the Improvement Activities Inventory in Tables F and G of the Appendix of this proposed rule.

For the Quality Payment Program Year 3 and future years, we are proposing to formalize an Annual Call for Activities process for adding possible new activities to the Improvement Activities Inventory. We believe this is a way to engage eligible clinician organizations and other relevant stakeholders, including beneficiaries, in the identification and submission of improvement activities for consideration. We propose that individual MIPS eligible clinicians or groups and other relevant stakeholders may recommend activities for potential inclusion in the Improvement Activities Inventory via a similar nomination form utilized in the transition year of MIPS found on the Quality Payment Program Web site at *www.qpp.cms.gov*. As part of the process, individual MIPS eligible clinicians, groups, and other relevant stakeholders would be able to nominate additional improvement activities that we may consider adding to the Improvement Activities Inventory. Individual MIPS eligible clinicians and groups and relevant stakeholders would be able to provide an explanation via the nomination form of how the improvement activity meets all the criteria we have identified in section II.C.6.e.(7)(b) of this proposed rule. The 2018 proposed new improvement activities and the 2018 proposed improvement activities with changes can be found in Tables F and G of the Appendix of this proposed rule and will be available on the CMS Web site.

We request comments on this proposed annual Call for Activities process.

(b) Criteria for Nominating New Improvement Activities for the Annual Call for Activities

We propose for the Quality Payment Program Year 2 and future years that stakeholders would apply one or more of the following criteria when submitting improvement activities in response to the Annual Call for Activities:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;

- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Activities that may be considered for an advancing care information bonus;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes; or
- CMS is able to validate the activity.

We note that in future rulemaking, activities that overlap with other performance categories may be included if such activities support the key goals of the program.

We request comments on this proposal.

(c) Submission Timeline for Nominating New Improvement Activities for the Annual Call for Activities

It is our intention that the nomination and acceptance process will, to the best extent possible, parallel the Annual Call for Measures process already conducted for MIPS quality measures. Aligned with this approach, we propose to accept submissions for prospective improvement activities at any time during the performance period for the Annual Call for Activities and create an Improvement Activities under Review (IAUR) list. This list will be considered by us and may include federal partners in collaboration with stakeholders. The IAUR list will be analyzed with consideration of the proposed criteria for inclusion of improvement activities in the Improvement Activities Inventory. In addition, we propose that for the Annual Call for Activities, only activities submitted by March 1 would be considered for inclusion in the Improvement Activities Inventory for the performance periods occurring in the following calendar year. This proposal is slightly different than the Call for Measures timeline. The Annual Call for Measures requires a 2-year implementation timeline because the measures being considered for inclusion in MIPS undergo the pre-rulemaking process with review by the Measures Application Partnership (MAP). We are not proposing that improvement activities undergo MAP review. Therefore, our intention is to close the Annual Call for Activities submissions by March 1 before the applicable performance period, which will enable us to propose the new improvement activities for adoption in the same year's rulemaking cycle for implementation in the following year. For example, an improvement activity submitted prior to March 1, 2018, would be considered for performance periods occurring in 2019. In addition, we propose that we will add new improvement activities to the inventory through notice-and-comment rulemaking. In future years we anticipate developing a process and establishing criteria for identifying activities for removal from the Improvement Activities Inventory through the Annual Call for Activities process. We are requesting comments on what criteria should be used to identify improvement activities for removal from the Improvement Activities Inventory.

(8) Approach for Adding New Subcategories

In the CY 2017 Quality Payment Program final rule (81 FR 77197), we finalized the following criteria for adding a new subcategory to the improvement activities performance category:

- The new subcategory represents an area that could highlight improved beneficiary health outcomes, patient engagement and safety based on evidence.
- The new subcategory has a designated number of activities that meet the criteria for an improvement activity and cannot be classified under the existing subcategories.
- Newly identified subcategories would contribute to improvement in patient care practices or improvement in performance on quality measures and cost performance categories.

We are not proposing any changes to the approach for adding new subcategories for the improvement activities performance category in this proposed rule. However, we are proposing that in future years of the Quality Payment Program we will add new improvement activities subcategories through notice-and-comment rulemaking. In addition, we are seeking comments on new improvement activities subcategories.

A number of stakeholders have suggested that a separate subcategory for improvement activities specifically related to health IT would make it easier for MIPS eligible clinicians and vendors to understand and earn points toward their final score through the use of health IT. Such a health IT subcategory could include only improvement activities that are specifically related to the advancing care information performance category measures and allow MIPS eligible clinicians to earn credit in the improvement activities performance category, while receiving a bonus in the advancing care information performance category as well. We are seeking suggestions on how a health IT subcategory within the improvement activities performance category could be structured to afford MIPS eligible clinicians with flexible opportunities to gain experience in using CEHRT and other health IT to improve their practice. Should the current policies where improvement activities earn bonus points within the advancing care information performance category be enhanced? Are there additional policies that should be explored in future rulemaking? We welcome public comment on this potential health IT subcategory.

(9) CMS Study on Burdens Associated With Reporting Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we finalized specifics regarding the CMS Study on Improvement Activities and Measurement including the study purpose, study participation credit and requirements, and the study procedure. We are modifying the name of the study in this proposed rule to the ''CMS study on burdens associated with reporting quality measures'' to more accurately reflect the purpose of the study. The study assesses clinician burden and data submission errors associated with the collection and submission of clinician quality measures for MIPS, enrolling groups of different sizes and individuals in both rural and non-rural settings and also different specialties. We also noted that study participants would receive full credit in the improvement activities performance category after successfully electing, participating, and submitting data to the study coordinators at CMS for the full calendar year (81 FR 77196). We requested comment on the study, and received generally supportive feedback for the study.

We are not proposing any changes to the study purpose. We are proposing changes to the study participation credit and requirements sample size, how the study sample is categorized into groups, and the frequency of quality data submission, focus groups, and surveys. In addition to performing descriptive statistics to compare the trends in errors and burden between study years 2017 and 2018, we would like to perform a more rigorous statistical analysis with the 2018 data, which will require a larger sample size. We propose this increase in the sample size for 2018 to

provide the minimum sample needed to get a significant result with adequate power for the following investigation.

Specifically, we are interested in whether there are any significant differences in quality measurement data submission errors and/or clinician burdens between rural clinicians submitting either individually or as a group, and urban clinicians submitting as an individual or as a group. A statistical power analysis was performed and a total sample size of 118 will be adequate for the main objective of the study. However, allowance will be made to account for attrition and other additional (or secondary) analysis.

This analysis would be compared at different sizes of practices (<3 eligible clinicians, between 3–8 eligible clinicians, etc.). This assessment is important since it facilitates tracing the root causes of measurement burdens and data submission errors that may be associated with any sub-group of clinician practice. This comparison may further break the sample down into more than four categories and a much larger sample size is a requisite for significant results with adequate probability of certainty.

The sample size for performance periods occurring in 2017 consisted of 42 MIPS groups as stated by MIPS criteria from the following seven categories:

- 10 urban individual or groups of <3 eligible clinicians.
- 10 rural individual or groups of <3 eligible clinicians.
- 10 groups of 3–8 eligible clinicians.
- 5 groups of 8–20 eligible clinicians.
- 3 groups of 20–100 eligible clinicians.
- 2 groups of 100 or greater eligible clinicians.
- 2 specialty groups.

We are proposing to increase the sample size for the performance periods occurring in 2018 to a minimum of:

- 20 urban individual or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).
- 20 rural individual or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).
- 10 groups of 3–8 eligible clinicians.
- 10 groups of 8–20 eligible clinicians.
- 10 groups of 20–100 eligible clinicians.
- 10 groups of 100 or greater eligible clinicians.
- 6 groups of >20 eligible clinicians reporting as individuals—(broken down into 3 urban & 3 rural).
- 6 specialty groups—(broken down into 3 reporting individually & 3 reporting as a group).
- Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

In addition, we are proposing changes to the study procedures. In the transition year of MIPS, study participants were required to attend a monthly focus group to share lessons learned in submitting quality data along with providing survey feedback to monitor effectiveness. However, an individual MIPS eligible clinician or group who chooses to report all 6 measures within a period of 90 days may not need to be a part of all of the focus groups and survey sessions after their first focus group and survey following the measurement data submission. This is because they may have nothing new to contribute in terms of discussion of errors or clinician burdens. This also applies to MIPS eligible clinicians that submit only three MIPS measures within the performance period, if they submitted all three measures within the 90-day period or at one submission. All study participants would participate in surveys and focus group meetings at least once after each measures data submission. For those who elect to report data for a 90-day period, we would make further engagement optional. Therefore, we are proposing that for Quality Payment Program Year 2 and future years that study participants would be required to attend as frequently as four monthly surveys and focus group sessions throughout the year, but certain study participants would be able to attend less frequently.

Further, the CY 2017 study requires study measurement data to be collected at baseline and at every 3 months (quarterly basis) afterwards for the duration of the calendar year. It also calls for a minimum requirement of three MIPS quality measures four times within the year. We believe this is inconsistent with clinicians reporting a full year's data as we believe some study participants may choose to submit data for all measures at one time, or alternatively, may choose to submit data up to six times during the 1-year period. We are proposing for the Quality Payment Program Year 2 and future years to offer study participants flexibility in their submissions so that they could submit once, as can occur in the MIPS program, and participate in study surveys and focus groups while still earning improvement activities credit.

It must be noted that although the aforementioned activities constitute an information collection request as defined in the implementing regulations of the Paperwork Reduction Act of 1995 (5 CFR 1320), the associated burden is exempt from application of the Paperwork Reduction Act. Specifically, section 1848(s)(7) of the Act, as added by section 102 of the MACRA (Pub. L. 114–10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures. Our goals for new measures are to develop new high quality, low cost measures that are meaningful, easily understandable and operable, and also, reliably and validly measure what they purport. This study shall inform us (and our contractors) on the root causes of clinicians' performance measure data collection and data submission burdens and challenges that hinders accurate and timely quality measurement activities. In addition, this study will inform us on the characteristic attributes that our new measures must possess to be able to accurately capture and measure the priorities and gaps MACRA aims for, as described in the Quality Measures Development Plan.[2] This study, therefore, serves as the initial stage of developing new measures and also adapting existing measures. We believe that understanding clinician's challenges and skepticisms, and especially, understanding the factors that undermine the optimal functioning and effectiveness of quality measures are requisites of developing measures that are not only measuring what it purports but also that are user friendly and understandable for frontline clinicians—our main stakeholders in measure development. This will lead to the creation of practice-derived, tested measures that reduces burden and create a culture of continuous improvement in measure development.

We request comments on our study on burdens associated with reporting quality measures proposals regarding sample size for the performance periods occurring in 2018, study procedures for the performance periods occurring in 2018 and future years, and data submissions for the performance periods occurring in 2018 and future years.

f. Advancing Care Information Performance Category

(1) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of CEHRT as a performance category under the MIPS. We refer to this performance

[2] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf* (assessed: 06/02/2017).

category as the advancing care information performance category, and it is reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the advancing care information performance category.

(2) Scoring

Section 1848(q)(5)(E)(i)(IV) of the Act states that 25 percent of the MIPS final score shall be based on performance for the advancing care information performance category. We established at § 414.1380(b)(4) that the score for the advancing care information performance category would be comprised of a base score, performance score, and potential bonus points for reporting on certain measures and activities. For further explanation of our scoring policies for the advancing care information performance category, we refer readers to 81 FR 77216–77227.

(a) Base Score

For the CY 2018 performance period, we are not proposing any changes to the base score methodology as established in the CY 2017 Quality Payment Program final rule (81 FR 77217–77223). We established the policy that MIPS eligible clinicians must report a numerator of at least one for the numerator/denominator measures, or a ''yes'' response for the yes/no measure in order to earn the 50 percentage points in the base score. In addition, if the base score requirements are not met, a MIPS eligible clinician would receive a score of zero for the ACI performance category.

(b) Performance Score

In the CY 2017 Quality Payment Program final rule (81 FR 77223 through 77226), we finalized that MIPS eligible clinicians can earn 10 percentage points in the performance score for meeting the Immunization Registry Reporting Measure. We believe we should modify this policy because we have learned that there are areas of the country where immunization registries are not available, and we did not intend to disadvantage MIPS eligible clinicians practicing in those areas. Thus, we are proposing to modify the scoring of the Public Health and Clinical Data Registry Reporting objective beginning with the performance period in CY 2018. We propose if a MIPS eligible clinician fulfills the Immunization Registry Reporting Measure, the MIPS eligible clinician would earn 10 percentage points in the performance score. If a MIPS eligible clinician cannot fulfill the Immunization Registry Reporting Measure, we are proposing that the MIPS eligible clinician could earn 5 percentage points in the performance score for each public health agency or clinical data registry to which the clinician reports for the following measures, up to a maximum of 10 percentage points: Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. A MIPS eligible clinician who chooses to report to more than one public health agency or clinical data registry may receive credit in the performance score for the submission to more than one agency or registry; however, the MIPS eligible clinician would not earn more than a total of 10 percentage points for such reporting.

We further propose similar flexibility for MIPS eligible clinicians who choose to report the measures specified for the Public Health Reporting Objective of the 2018 Advancing Care Information Transition Objective and Measure set. (In section II.C.6.f.(6)(b) of this proposed rule, we are proposing to allow MIPS eligible clinicians to report using the 2018 Advancing Care Information Transition Objectives and Measures in 2018.) We propose if a MIPS eligible clinician fulfills the Immunization Registry Reporting Measure, the MIPS eligible clinician would earn 10 percentage points in the performance score. If a MIPS eligible clinician cannot fulfill the Immunization Registry Reporting Measure, we are proposing that the MIPS eligible clinician could earn 5 percentage points in the performance score for each public health agency or specialized registry to which the clinician reports for the following measures, up to a maximum of 10 percentage points: Syndromic Surveillance Reporting; Specialized Registry Reporting. A MIPS eligible clinician who chooses to report to more than one specialized registry or public health agency to submit syndromic surveillance data may earn 5 percentage points in the performance score for reporting to each one, up to a maximum of 10 percentage points.

By proposing to expand the options for fulfilling the Public Health and Clinical Data Registry Reporting and the Public Health Reporting objectives, we believe that we are adding flexibility so that additional MIPS eligible clinicians can successfully fulfill this objective and earn 10 percentage points in the performance score. We are not proposing to change the maximum performance score that a MIPS eligible clinician can earn; it remains at 90 percent.

We are inviting public comment on these proposals.

(c) Bonus Score

In the CY 2017 Quality Payment Program final rule (81 FR 77220 through 77226), for the Public Health and Clinical Data Registry Reporting objective and the Public Health Reporting objective, we finalized that MIPS eligible clinicians who report to one or more public health agencies or clinical data registries beyond the Immunization Registry Reporting Measure will earn a bonus score of 5 percentage points in the advancing care information performance category. (In section II.C.6.f.(6)(b) of this proposed rule, we are proposing to allow MIPS eligible clinicians to report using the 2018 Advancing Care Information Transition Objectives and Measures in 2018.) Based on our proposals above to allow MIPS eligible clinicians who cannot fulfill the Immunization Registry Reporting Measure to earn additional points in the performance score, we believe we should modify this policy so that MIPS eligible clinicians cannot earn points in both the performance score and bonus score for reporting to the same public health agency or clinical data registry. We are proposing to modify our policy beginning with the performance period in CY 2018. We are proposing that a MIPS eligible clinician may only earn the bonus score of 5 percentage points for reporting to at least one additional public health agency or clinical data registry that is different from the agency/agencies or registry/or registries to which the MIPS eligible clinician reports to earn a performance score. For example, if a MIPS eligible clinician reports to a public health agency and a clinical data registry for the performance score, they could earn the bonus score of 5 percentage points by reporting to a different agency or registry that the clinician did not identify for purposes of the performance score. A MIPS eligible clinician would not receive credit under both the performance score and bonus score for reporting to the same agency or registry.

We are proposing that for the Advancing Care Information Objectives and Measures, a bonus of 5 percentage points would be awarded if the MIPS eligible clinician reports ''yes'' for any one of the following measures associated with the Public Health and Clinical Data Registry Reporting

objective: Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; or Clinical Data Registry Reporting. We are proposing that for the 2018 Advancing Care Information Transition Objectives and Measures, a bonus of 5 percent would be awarded if the MIPS eligible clinician reports ''yes'' for any one of the following measures associated with the Public Health Reporting objective: Syndromic Surveillance Reporting or Specialized Registry Reporting. We are proposing that to earn the bonus score, the MIPS eligible clinician must be in active engagement with one or more additional public health agencies or clinical data registries that is/are different from the agency or registry that they identified to earn a performance score.

We are inviting public comment on this proposal.

(d) Improvement Activities Bonus Score Under the Advancing Care Information Performance Category

In the CY 2017 Quality Payment Program final rule (81 FR 77202), we discussed our approach to the measurement of the use of health IT to allow MIPS eligible clinicians and groups the flexibility to implement health IT in a way that supports their clinical needs. In addition, we discussed the need to move toward measurement of health IT use with respect to its contribution to effective care coordination and improving outcomes for patients. We stated that this approach would allow us to more directly link health IT adoption and use to patient outcomes, moving MIPS beyond the measurement of EHR adoption and process measurement and into a more patient-focused health IT program. Toward that end, we adopted a policy to award a bonus score to MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category based on our belief that the use of CEHRT in carrying out these activities could further the outcomes of clinical practice improvement.

We adopted a final policy to award a 10 percent bonus for the advancing care information performance category if a MIPS eligible clinician attests to completing at least one of the improvement activities we have specified using CEHRT (81 FR 77209). We refer readers to Table 8 in the CY 2017 Quality Payment Program final rule (81 FR 77202–77209) for a list of the improvement activities eligible for the advancing care information performance category bonus. In this proposed rule, we are proposing to expand this policy beginning with the CY 2018 performance period by identifying additional improvement activities in Table 6 that would be eligible for the advancing care information performance category bonus score if they are completed using CEHRT functionality. The activities eligible for the bonus score would include those listed in Table 6, as well as those listed in Table 8 in last year's final rule. We refer readers to the Improvement Activities section of this proposed rule (section II.C.6.e. of this proposed rule) for a discussion of the proposed new improvement activities and proposed changes to the improvement activities for 2018.

Ten percentage points is the maximum bonus a MIPS eligible clinician would receive if they attest to using CEHRT for one or more of the activities we have identified as eligible for the bonus. This bonus is intended to support progression toward holistic health IT use and measurement; attesting to even one improvement activity demonstrates that the MIPS eligible clinician is working toward this holistic approach to the use of their CEHRT. The weight of the improvement activity for the improvement activities performance category has no effect on the bonus awarded in the advancing care information performance category.

We invite comment on this proposal.

TABLE 6: Proposed New Improvement Activities Eligible for the Advancing Care Information Performance Category Bonus Beginning with the 2018 Performance Period

Improvement Activity Performance Category Subcategory	Activity Name	Activity	Improvement Activity Performance Category Weight	Related Advancing Care Information Measure(s)*
Patient Safety and Practice Assessment	Communication of Unscheduled Visit for Adverse Drug Event and Nature of Event	A MIPS eligible clinician providing unscheduled care (such as an emergency room, urgent care, or other unplanned encounter) attests that, for greater than 75 percent of case visits that result from a clinically significant adverse drug event, the MIPS eligible clinician transmits information, including through the use of health IT to the patient's primary care clinician regarding both the unscheduled visit and the nature of the adverse drug event within 48 hours. A clinically significant adverse event is defined as a medication-related harm or injury such as side-effects, supratherapeutic effects, allergic reactions, laboratory abnormalities, or medication errors requiring urgent/emergent evaluation, treatment, or hospitalization.	Medium	Secure Messaging Send A Summary of Care Request/Accep t Summary of Care
Patient Safety and Practice Assessment	Consulting AUC using clinical decision support when ordering advanced diagnostic imaging	A MIPS eligible clinician would attest that they are consulting specified applicable appropriate use criteria (AUC) through a qualified clinical decision support mechanism for all advanced diagnostic imaging services ordered. This activity is for clinicians that are early adopters of the Medicare AUC program (e.g., 2018 performance year) and for clinicians that begin the program in future years as will be required by CFR §414.94 (authorized by the Protecting Access to Medicare Act of 2014). Qualified mechanisms will be able to provide a report to the ordering clinician that can be used to assess patterns of image-ordering and improve upon those patterns to ensure that patients are receiving the most appropriate imaging for their individual condition.	High	Clinical Decision Support (CEHRT function only)
Population Management	Glycemic Screening Services	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 75 percent of medical records with documentation of screening patients for abnormal blood glucose according to current U.S. Preventive Services Task Force (USPSTF) and/or Americans Diabetes Association (ADA) guidelines.	Medium	Patient-Specific Education Patient Generated Health Data or Data from Non-clinical Settings
Population Management	Glycemic Referring Services	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 75 percent of medical records with documentation of referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program.	Medium	Patient-Specific Education Patient Generated Health Data or Data from Non-clinical Settings

Improvement Activity Performance Category Subcategory	Activity Name	Activity	Improvement Activity Performance Category Weight	Related Advancing Care Information Measure(s)*
Population Management	Provide Clinical-Community Linkages	Engaging community health workers to provide a comprehensive link to community resources through family-based services focusing on success in health, education, and self-sufficiency. This activity supports individual MIPS eligible clinicians or groups that coordinate with primary care and other clinicians, engage and support patients, use of health information technology, and employ quality measurement and improvement processes. An example of this community based program is the NCQA Patient-Centered Connected Care (PCCC) Recognition Program or other such programs that meet these criteria.	Medium	Provide Patient Access Patient-Specific Education Patient-Generated Health Data
Population Management	Advance Care Planning	Implementation of practices/processes to develop advance care planning that includes: documenting the advance care plan or living will within the medical record, educating clinicians about advance care planning motivating them to address advance care planning needs of their patients, and how these needs can translate into quality improvement, educating clinicians on approaches and barriers to talking to patients about end-of-life and palliative care needs and ways to manage its documentation, as well as informing clinicians of the healthcare policy side of advance care planning.	Medium	Patient-Generated Health Data Patient Specific Education
Achieving Health Equity	Promote use of patient-reported outcome tools	Promote use of patient-reported outcome tools Demonstrate performance of activities for employing patient-reported outcome (PRO) tools and corresponding collection of PRO data (e.g., use of PQH-2 or PHQ-9 and PROMIS instruments) such as patient reported Wound Quality of Life (QoL), patient reported Wound Outcome, and patient reported Nutritional Screening.	High	Public Health Registry Reporting Clinical Data Registry Reporting Patient-Generated Health Data
Care Coordination	Practice Improvements that Engage Community Resources to Support Patient Health Goals	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: • Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; • Including through the use of tools that facilitate electronic communication between settings; • Screen patients for health-harming legal needs; and/or Provide a guide to available community resources.	Medium	Send a Summary of Care Request/Accept Summary of Care Patient-Generated Health Data

Improvement Activity Performance Category Subcategory	Activity Name	Activity	Improvement Activity Performance Category Weight	Related Advancing Care Information Measure(s)*
Care Coordination	Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients	The primary care and behavioral health practices use the same electronic health record system for shared patients or have an established bidirectional flow of primary care and behavioral health records.	Medium	Send a Summary of Care Request/Accept Summary of Care
Care Coordination	PSH Care Coordination	Participation in a Perioperative Surgical Home (PSH) that provides a patient-centered, physician-led, interdisciplinary, and team-based system of coordinated patient care, which coordinates care from pre-procedure assessment through the acute care episode, recovery, and post-acute care. This activity allows for reporting of strategies and processes related to care coordination of patients receiving surgical or procedural care within a PSH. The clinician must perform one or more of the following care coordination activities: • Coordinate with care managers/navigators in preoperative clinic to plan and implementation comprehensive post discharge plan of care; • Deploy perioperative clinic and care processes to reduce post-operative visits to emergency rooms; • Implement evidence-informed practices and standardize care across the entire spectrum of surgical patients; or • Implement processes to ensure effective communications and education of patients' post-discharge instructions.	Medium	Send a Summary of Care Request/Accept Summary of Care Clinical Information Reconciliation Health Information Exchange

Improvement Activity Performance Category Subcategory	Activity Name	Activity	Improvement Activity Performance Category Weight	Related Advancing Care Information Measure(s)*
Beneficiary Engagement	Engage Patients and Families to Guide Improvement in the System of Care	Engage patients and families to guide improvement in the system of care by leveraging digital tools for ongoing guidance and assessments outside the encounter, including the collection and use of patient data for return-to-work and patient quality of life improvement. Platforms and devices that collect patient-generated health data (PGHD) must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient. Includes patient reported outcomes (PROs). Examples include patient engagement and outcomes tracking platforms, cellular or web-enabled bi-directional systems, and other devices that transmit clinically valid objective and subjective data back to care teams. Because many consumer-grade devices capture PGHD (for example, wellness devices), platforms or devices eligible for this improvement activity must be, at a minimum, endorsed and offered clinically by care teams to patients to automatically send ongoing guidance (one way). Platforms and devices that additionally collect PGHD must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient (e.g. automated patient-facing instructions based on glucometer readings). Therefore, unlike passive platforms or devices that may collect but do not transmit PGHD in real or near-real time to clinical care teams, active devices and platforms can inform the patient or the clinical care team in a timely manner of important parameters regarding a patient's status, adherence, comprehension, and indicators of clinical concern.	High	Patient-Generated Health Data Provide Patient Access View, Download, or Transmit

(3) Performance Periods for the Advancing Care Information Performance Category

In the CY 2017 Quality Payment Program final rule (81 FR 77210 through 77211), we established a performance period for the advancing care information performance category to align with the overall MIPS performance period of one full year to ensure all four performance categories are measured and scored based on the same period of time. We believe this will lower reporting burden, focus clinician quality improvement efforts and align administrative actions so that MIPS eligible clinicians can use common systems and reporting pathways. We stated for the first and second performance periods of MIPS (CYs 2017 and 2018), we will accept a minimum of 90 consecutive days of data and encourage MIPS eligible clinicians to report data for the full year performance period. We are maintaining this policy as finalized for the performance period in CY 2018, and will accept a minimum of 90 consecutive days of data in CY 2018. We are proposing the same policy for the advancing care information performance category for the performance period in CY 2019, Quality Payment Program Year 3, and would accept a minimum of 90 consecutive days of data in CY 2019. We refer readers to section II.C.5. in this proposed rule for additional information on the MIPS performance period.

(4) Certification Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77211 through 77213), we outlined the requirements for MIPS eligible clinicians using CEHRT during the CY 2017 performance period for the advancing care information performance category as it relates to the objectives and measures they select to report, and also outlined requirements for the CY 2018 performance period. We additionally adopted a definition of CEHRT at § 414.1305 for MIPS eligible clinicians that is based on the definition that applies in the EHR Incentive Programs under § 495.4.

For the CY 2017 performance period, we adopted a policy by which MIPS eligible clinicians may use EHR

technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two. For the CY 2018 performance period, we previously stated that MIPS eligible clinicians must use EHR technology certified to the 2015 Edition to meet the objectives and measures specified for the advancing care information performance category.

We received significant comments and feedback from stakeholders requesting that we extend the use of 2014 Edition CEHRT beyond CY 2017 into CY 2018 and even CY 2019. Many commenters noted the lack of products certified to the 2015 Edition. Others stated that switching from the 2014 Edition to the 2015 Edition requires a large amount of time and planning and if it is rushed there is a potential risk to patient health. Some commenters noted the significant burden of combining outputs from multiple CEHRTs. A few mentioned that the cost to switch to the 2015 Edition is prohibitive for smaller practices.

Our experience with the transition from EHR technology certified to the 2011 Edition to EHR technology certified to the 2014 Edition did make us aware of the many issues associated with the adoption of EHR technology certified to a new Edition. These include the time that will be necessary to effectively deploy EHR technology certified to the 2015 Edition standards and certification criteria and to make the necessary patient safety, staff training, and workflow investments to be prepared to report for the advancing care information performance category for 2018. We understand and appreciate these concerns, and are working in collaboration with our federal partners at the Office of the National Coordinator for Health Information Technology (ONC) to monitor progress on the 2015 Edition upgrade.

As noted in the FY 2018 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System proposed rule (referred to as the FY 2018 IPPS/LTCH PPS proposed rule) (82 FR 20136), ONC is working with health IT developers to analyze and monitor the status of developer readiness for 2015 Edition technology. As part of these analyses, ONC also reviewed health IT being certified to 2015 Edition by health IT developers who have products that were certified for the 2014 Edition and were used by EHR Incentive Program participants to attest. This analysis compared the pace of 2014 Edition certification with the pace of 2015 Edition certification to date. As of the beginning of the second quarter of CY 2017, ONC confirmed that at least 53 percent of eligible clinicians and 80 percent of eligible hospitals have 2015 Edition certified EHR technology available based on previous EHR Incentive Programs attestation data. Based on these data, and as compared to the transition from 2011 Edition to 2014 Edition, it appears that the transition from the 2014 Edition to the 2015 Edition is on schedule for the CY 2018 performance period.

However, the analysis also considered market trends such as consolidation and the number of large and small developers covering various groups of participants and the potential impact on readiness. The eligible hospital market is fairly concentrated, with nearly 98 percent of eligible hospital EHR Incentive Program participants using health IT from the top ten developers (ranked by market share) with a significant majority of that coverage by the top five developers. For hospitals, some developers representing a smaller market share also have certified health IT already available and are not expected to have a release schedule much different from their larger competitors. Considering market factors and using previous EHR Incentive Programs attestation data, ONC estimates that at least 85 percent of eligible hospitals would have EHR technology certified to the 2015 Edition available for use by the end of CY 2017 for program participation in 2018. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136), we proposed to shorten the EHR reporting period to a minimum of any continuous 90-day period within CY 2018 for eligible hospitals and CAHs, as well as EPs who attest for a state's Medicaid EHR Incentive Program, to allow additional time for successful implementation of EHR technology certified to the 2015 Edition in CY 2018.

For MIPS eligible clinicians, the concern of potential impact on participation readiness when reviewing these market factors may be more significant. As noted in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136), historical data indicates eligible professionals were more likely to use a wider range of certified health IT, including those which individually make up a smaller segment of the overall market. Therefore, when market factors are taken into account, there exists a larger proportion of readiness that is unknown due to the wider range of certified health IT which may be used by MIPS eligible clinicians. This necessitated a more conservative approach for MIPS eligible clinician readiness. That estimate is that 74 percent of MIPS eligible clinicians will be ready to participate in MIPS using 2015 Edition certified EHR technologies by January 1, 2018.

However, subsequent to the preliminary analysis, ONC has continued to monitor readiness and to receive feedback from stakeholders on factors influencing variations in the development and implementation timelines for developers supporting different segments of the market, as well as the relationship between the developer readiness timeline and participant readiness. This continuing analysis supports a potential need for a longer implementation timeline for MIPS eligible clinicians. Stakeholder feedback suggests that while the estimate for known readiness remains the same, readiness among the remaining MIPS eligible clinicians may not be on the same timeline. About one quarter of eligible professional EHR Incentive Program participants in prior years used certified health IT from small developers that each has an historical market share of 1 percent or less. Therefore, MIPS eligible clinicians will need a significant number of smaller developers to reach the same readiness on the same timeline as larger companies in order to support program participants seeking to upgrade to the 2015 Edition. However, small developers generally offer a limited number or type of products, and may have more limited resources to dedicate to upgrade development, testing and certification, and implementation, which may affect availability and timing. In addition, the same factors may impact the capacity of some developers to support participants during the process and therefore the timeline for participant readiness would also potentially be longer. This is supported by historical analysis as a smaller percentage of eligible professionals used 2014 Edition certified EHR technology for participation in the EHR Incentive Programs during the 2014 calendar year than eligible hospitals and CAHs for the same year. For this reason, we believe additional flexibility for MIPS eligible clinicians is essential to support successful participation in the advancing care information performance category.

We continue to believe that there are many benefits for switching to EHR technology certified to the 2015 Edition. As noted in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20136), the 2015 Edition health IT certification criteria enables health information exchange through new and enhanced certification criteria standards, and through implementation specifications

for interoperability. The 2015 Edition also incorporates changes that are designed to spur innovation and provide more choices to health care providers and patients for the exchange of electronic health information, including new Application Programming Interface (API) certification criteria. APIs are required for patient engagement measures within the advancing care information category; however, they may also be enabled by a health care provider or organization for their own use of third party applications with their CEHRT, such as for quality improvement. An API can also be enabled by a health care provider to give patients access to their health information through a third-party application with more flexibility than is often found in many current patient portals. From the MIPS eligible clinician perspective, an API could complement a patient portal or could also potentially make one unnecessary if patients are able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party. In addition, the 2015 Edition health IT transitions of care certification criterion rigorously assesses a product's ability to create and receive a Consolidated-Clinical Document Architecture (C–CDA) formatted documents. The ONC also adopted certification criteria that both support interoperability in other settings and use cases, such as the Common Clinical Data Set summary record, data segmentation for privacy, and care plan certification criteria (80 FR 62603).

However, in light of the conservative readiness estimates for MIPS eligible clinicians, and in line with our commitment to supporting small practices, solo practitioners and specialties which may be more likely to use certified health IT offered by small developers, we are proposing that MIPS eligible clinicians may use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the CY 2018 performance period. We propose to amend § 414.1305 to reflect this change. We further note, that to encourage new participants to adopt certified health IT and to incentivize participants to upgrade their technology to 2015 Edition products which better support interoperability across the care continuum, we are proposing to offer a bonus of 10 percentage points under the advancing care information performance category for MIPS eligible clinicians who report the Advancing Care Information Objectives and Measures for the performance period in CY 2018 using only 2015 Edition CEHRT. We are proposing to amend § 414.1380(b)(4)C)(3) to reflect this change. We are proposing this one-time bonus for CY 2018 to support and recognize MIPS eligible clinicians and groups that invest in implementing certified EHR technology in their practice. Specifically, we intend this bonus to support new participants that may be adopting health IT for the first time in CY 2018 and do not have 2014 Edition technology available to use or that may have no prior experience with meaningful use objectives and measures. We believe this bonus will help recognize their investment to adopt health IT and support their participation in the advancing care information performance category in MIPS. In addition, we believe this bonus will help to incentivize participants to continue the process of upgrading from 2014 Edition to 2015 Edition, especially small practices where the investment in updated workflows and implementation may present unique challenges. We intend this bonus to support and recognize their efforts to engage with the advancing care information measures using technology certified to the 2015 Edition, which include more robust measures using updated standards and functions which support interoperability. We seek comment on this proposed bonus. Specifically, we seek comment on if the percentage of the bonus is appropriate, or whether it should be limited to new participants in MIPS and small practices.

This bonus is not available to MIPS eligible clinicians who use a combination of the 2014 and 2015 Editions. We note that with the addition of the 2015 Edition CEHRT bonus of 10 percentage points, MIPS eligible clinicians would be able to earn a bonus score of up to 25 percentage points in CY 2018 under the advancing care information performance category, an increase from the 15 percentage point bonus score available in CY 2017.

To facilitate readers in identifying the requirements of CEHRT for the Advancing Care Information Objectives and Measures, we are including Table 8 in section II.C.6.f.(6)(a) which lists the 2015 Edition and 2014 Edition certification criteria required to meet the objectives and measures.

We invite comments on these proposals.

(5) Scoring Methodology Considerations

Section 1848(q)(5)(E)(i)(IV) of the Act states that 25 percent of the MIPS final score shall be based on performance for the advancing care information performance category. Further, section 1848(q)(5)(E)(ii) of the Act, provides that in any year in which the Secretary estimates that the proportion of eligible professionals (as defined in section 1848(o)(5) of the Act) who are meaningful EHR users (as determined under section 1848(o)(2) of the Act) is 75 percent or greater, the Secretary may reduce the applicable percentage weight of the advancing care information performance category in the MIPS final score, but not below 15 percent, and increase the weightings of the other performance categories such that the total percentage points of the increase equals the total percentage points of the reduction. We note that section 1848(o)(5) of the Act defines an eligible professional as a physician, as defined in section 1861(r) of the Act.

In CY 2017 Quality Payment Program final rule (81 FR 77226–77227), we established a final policy, for purposes of applying section 1848(q)(5)(E)(ii) of the Act, to estimate the proportion of physicians as defined in section 1861(r) of the Act who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of at least 75 percent for a performance period. We established that we will base this estimation on data from the relevant performance period, if we have sufficient data available from that period. For example, if feasible, we would consider whether to reduce the applicable percentage weight of the advancing care information performance category in the MIPS final score for the 2019 MIPS payment year based on an estimation using the data from the 2017 performance period. We stated that we will not include in the estimation physicians for whom the advancing care information performance category is weighted at zero percent under section 1848(q)(5)(F) of the Act, which we relied on in the CY 2017 Quality Payment Program final rule (81 FR 77226 through 77227) to establish policies under which we would weigh the advancing care information performance category at zero percent of the final score. In addition, we are proposing not to include in the estimation physicians for whom the advancing care information performance category would be weighted at zero percent under our proposal in section II.C.6.f.(7) of this proposed rule to implement certain provisions of the 21st Century Cures Act (that is, physicians who are determined hospital-based or ambulatory surgical center-based, or who are granted an exception based on

significant hardship or decertified EHR technology.

We are considering modifications to the policy we established in last year's rulemaking to base our estimation of physicians who are meaningful EHR users for a MIPS payment year (for example, 2019) on data from the relevant performance period (for example, 2017). We are concerned that if in future rulemaking we decide to propose to change the weight of the advancing care information performance category based on our estimation, such a change may cause confusion to MIPS eligible clinicians who are adjusting to the MIPS program and believe this performance category will make up 25 percent of the final score for the 2019 MIPS payment year. The earliest we would be able to make our estimation based on 2017 data and propose in future rulemaking to change the weight of the advancing care information performance category for the 2019 MIPS payment year would be in mid-2018, as the deadline for data submission is March 31, 2018. We are requesting public comments on whether this timeframe is sufficient, or whether a more extended timeframe would be preferable. We are proposing to modify our existing policy such that we would base our estimation of physicians who are meaningful EHR users for a MIPS payment year on data from the performance period that occurs four years before the MIPS payment year. For example, we would use data from the 2017 performance period to estimate the proportion of physicians who are meaningful EHR users for purposes of reweighting the advancing care information performance category for the 2021 MIPS payment year.

We invite comments on this proposal.

(6) Objectives and Measures

(a) Advancing Care Information Objectives and Measures Specifications

We are proposing to maintain for the CY 2018 performance period the Advancing Care Information Objectives and Measures as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77227 through 77229) with the modifications proposed below. As we noted (81 FR 77227), these objectives and measures were adapted from the Stage 3 objectives and measures finalized in the 2015 EHR Incentive Programs final rule (80 FR 62829 through 62871), however, we did not maintain the previously established thresholds for MIPS. For a more detailed discussion of the Stage 3 objectives and measures, including explanatory material and defined terms, we refer readers to the 2015 EHR Incentive Programs final rule (80 FR 62829 through 62871).

TABLE 7: 2018 Performance Period Advancing Care Information Performance Category Scoring Methodology
Advancing Care Information Objectives and Measures

2018 Advancing Care Information Objective	2018 Advancing Care Information Measure*	Required/ Not Required for Base Score (50%)	Performance Score (up to 90%)	Reporting Requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement
Electronic Prescribing	e-Prescribing	Required	0	Numerator/ Denominator
Patient Electronic Access	Provide Patient Access	Required	Up to 10%	Numerator/ Denominator
	Patient-Specific Education	Not Required	Up to 10%	Numerator/ Denominator
Coordination of Care Through Patient Engagement	View, Download, or Transmit (VDT)	Not Required	Up to 10%	Numerator/ Denominator
	Secure Messaging	Not Required	Up to 10%	Numerator/ Denominator
	Patient-Generated Health Data	Not Required	Up to 10%	Numerator/ Denominator
Health Information Exchange	Send a Summary of Care	Required	Up to 10%	Numerator/ Denominator
	Request/Accept Summary of Care	Required	Up to 10%	Numerator/ Denominator
	Clinical Information Reconciliation	Not Required	Up to 10%	Numerator/ Denominator
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Not Required	0 or 10%	Yes/No Statement
	Syndromic Surveillance Reporting	Not Required	0 or 5%*	Yes/No Statement
	Electronic Case Reporting	Not Required	0 or 5%*	Yes/No Statement
	Public Health Registry Reporting	Not Required	0 or 5%*	Yes/No Statement
	Clinical Data Registry Reporting	Not Required	0 or 5%*	Yes/No Statement
Bonus (up to 25%)				
Report to one or more additional public health agencies or clinical data registries beyond those identified for the performance score		5% bonus		Yes/No Statement
Report improvement activities using CEHRT		10% bonus		Yes/No Statement
Report using only 2015 Edition CEHRT		10% bonus		Based upon measures submitted

* A MIPS eligible clinician who cannot fulfill the Immunization Registry Reporting Measure may earn 5% for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10% under the performance score.

Objective: Protect Patient Health Information.

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing.

Objective: Generate and transmit permissible prescriptions electronically.

E-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.
- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Objective: Patient Electronic Access.

Objective: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Provide Patient Access Measure: For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's CEHRT.

- *Denominator:* The number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.

Definition of timely—Beginning with the 2018 performance period, we are proposing to define ''timely'' as within 4 business days of the information being available to the MIPS eligible clinician. This definition of timely is the same as we adopted under the EHR Incentive Programs (80 FR 62815).

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

- *Denominator:* The number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the performance period.

Objective: Coordination of Care Through Patient Engagement.

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician. A MIPS eligible clinician may meet the measure by either (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's CEHRT; or (3) a combination of (1) and (2).

Proposed change to the View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician by either (1) viewing, downloading or transmitting to a third party their health information; or (2) accessing their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's CEHRT; or (3) a combination of (1) and (2). We are proposing this change because we erroneously described the actions in the measure (viewing, downloading or transmitting; or accessing through an API) as being taken by the MIPS eligible clinician rather than the patient or the patient-authorized representatives. This change would align the measure description with the requirements of the numerator and denominator. We propose this change would apply beginning with the performance period in 2017.

- *Denominator:* Number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

Secure Messaging Measure: For at least one unique patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

- *Denominator:* Number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Patient-Generated Health Data Measure: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for at least one unique patient seen by the MIPS eligible clinician during the performance period.

- *Denominator:* Number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator for whom data from non-clinical settings, which may

include patient-generated health data, is captured through the CEHRT into the patient record during the performance period.

Objective: Health Information Exchange

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care clinician into their EHR using the functions of CEHRT.

Proposed Change to the Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.

We inadvertently used the term ''health care clinician'' and are proposing to replace it with the more appropriate term ''health care provider''. We are proposing this change would apply beginning with the performance period in 2017.

Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care clinician (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Proposed Change to the Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

We inadvertently used the term ''health care clinician'' and are proposing to replace it with the more appropriate term ''health care provider''. We are proposing this change would apply beginning with the 2017 performance period.

- *Denominator:* Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.
- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Request/Accept Summary of Care Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

- *Denominator:* Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
- *Numerator:* Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the CEHRT.

Clinical Information Reconciliation Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The MIPS eligible clinician must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known medication allergies; (3) Current Problem list. Review of the patient's current and active diagnoses.

- *Denominator:* Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.
- *Numerator:* The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

Objective: Public Health and Clinical Data Registry Reporting.

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

We note that the functionality to be bi-directional is part of EHR technology certified to the 2015 Edition (80 FR 62554). It means that in addition to sending the immunization record to the immunization registry, the CEHRT must be able to receive and display a consolidated immunization history and forecast.

Syndromic Surveillance Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting where the jurisdiction accepts syndromic data from such settings and the standards are clearly defined.

Proposed Change to the Syndromic Surveillance Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data. We are proposing this change because we inadvertently finalized the measure description that we had proposed for Stage 3 of the EHR Incentive Program (80 FR 82866) and not the measure description that we finalized (80 FR 82970). The proposed change aligns with the measure description finalized for Stage 3.

Electronic Case Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

Public Health Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

Clinical Data Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

We note that we have split the Specialized Registry Reporting Measure that we adopted under the 2017 Advancing Care Information Transition Objectives and Measures into two separate measures, Public Health Registry and Clinical Data Registry Reporting to better define the registries available for reporting. We want to continue to encourage those MIPS eligible clinicians who have already started down the path of reporting to a specialized registry to continue to engage in public health and clinical data registry reporting. Therefore, we propose to allow MIPS eligible clinicians and groups to continue to count active engagement in electronic

public health reporting with specialized registries. We propose to allow these registries to be counted for purposes of reporting the Public Health Registry Reporting Measure or the Clinical Data Registry Reporting Measure beginning with the 2018 performance period. A MIPS eligible clinician may count a specialized registry if the MIPS eligible clinician achieved the phase of active engagement as described under ''active engagement option 3: production'' in the 2015 EHR Incentive Programs final rule with comment period (80 FR 62862 through 62865), meaning the clinician has completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry.

As noted previously, to facilitate readers in identifying the requirements of CEHRT for the Advancing Care Information Objectives and Measures, we are including the following Table 8, which includes the 2015 Edition and 2014 Edition certification criteria required to meet the objectives and measures.

TABLE 8—ADVANCING CARE INFORMATION OBJECTIVES AND MEASURES AND CERTIFICATION CRITERIA FOR 2014 AND 2015 EDITIONS

Objective	Measure	2015 Edition	2014 Edition
Protect Patient Health Information.	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.	The requirements are included in the Base EHR Definition.
Electronic Prescribing ..	e-Prescribing	§ 170.315(b)(3) (Electronic Prescribing). § 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks.	§ 170.314(b)(3) (Electronic Prescribing). § 170.314(a)(10) (Drug-Formulary and Preferred Drug List checks.
Patient Electronic Access.	Provide Patient Access.	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party). § 170.315(g)(7) (Application Access—Patient Selection). § 170.315(g)(8) (Application Access—Data Category Request). § 170.315(g)(9) (Application Access—All Data Request) The three criteria combined are the ''API'' certification criteria.	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).
Patient Electronic Access.	Patient Specific Education.	§ 170.315(a)(13) (Patient-specific Education Resources).	§ 170.314(a)(13) (Patient-specific Education Resources).
Coordination of Care Through Patient Engagement.	View, Download, or Transmit (VDT).	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party). § 170.315(g)(7) (Application Access—Patient Selection). § 170.315(g)(8) (Application Access—Data Category Request). § 170.315(g)(9) (Application Access—All Data Request) The three criteria combined are the ''API'' certification criteria.	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).
Coordination of Care Through Patient Engagement.	Secure Messaging	§ 170.315(e)(2) (Secure Messaging)	§ 170.314(e)(3) (Secure Messaging).
Coordination of Care Through Patient Engagement.	Patient-Generated Health Data.	§ 170.315(e)(3) (Patient Health Information Capture) Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.	N/A.
Health Information Exchange.	Send a Summary of Care.	§ 170.315(b)(1) (Transitions of Care)	§ 170.314(b)(2) (Transitions of Care-Create and Transmit Transition of Care/Referral Summaries or § 170.314(b)(8) (Optional—Transitions of Care).
Health Information Exchange.	Request/Accept Summary of Care.	§ 170.315(b)(1) (Transitions of Care)	§ 170.314(b)(1) (Transitions of Care-Receive, Display and Incorporate Transition of Care/Referral Summaries or § 170.314(b)(8) (Optional-Transitions of Care).
Health Information Exchange.	Clinical Information Reconciliation.	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).	§ 170.314(b)(4) (Clinical Information Reconciliation or § 170.314(b)(9) (Optional—Clinical Information Reconciliation and Incorporation).
Public Health and Clinical Data Registry Reporting.	Immunization Registry Reporting.	§ 170.315(f)(1) (Transmission to Immunization Registries).	N/A.
Public Health and Clinical Data Registry Reporting.	Syndromic Surveillance Reporting.	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Setting Only.	§ 170.314(f)(3) (Transmission to Public Health Agencies—Syndromic Surveillance) or § 170.314(f)(7) (Optional-Ambulatory Setting Only-Transmission to Public Health Agencies—Syndromic Surveillance).
Public Health and Clinical Data Registry Reporting.	Electronic Case Reporting.	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).	N/A.

TABLE 8—ADVANCING CARE INFORMATION OBJECTIVES AND MEASURES AND CERTIFICATION CRITERIA FOR 2014 AND 2015 EDITIONS—Continued

Objective	Measure	2015 Edition	2014 Edition
Public Health and Clinical Data Registry Reporting.	Public Health Registry Reporting.	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries). § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).	§ 170.314(f)(5) (Optional—Ambulatory Setting Only—Cancer Case Information and § 170.314(f)(6) (Optional—Ambulatory Setting Only—Transmission to Cancer Registries).
Public Health and Clinical Data Registry Reporting.	Clinical Data Registry Reporting.	No 2015 Edition health IT certification criteria at this time.	N/A.

We are inviting public comment on these proposals.

(b) 2017 and 2018 Advancing Care Information Transition Objectives and Measures Specifications

TABLE 9—ADVANCING CARE INFORMATION PERFORMANCE CATEGORY SCORING METHODOLOGY FOR 2018 ADVANCING CARE INFORMATION TRANSITION OBJECTIVES AND MEASURES

2018 Advancing Care Information Transition Objective	2018 Advancing Care Information Transition Measure	Required/ not required for base score (50%)	Performance Score (up to 90%)	Reporting requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement.
Electronic Prescribing	E-Prescribing	Required	0	Numerator/Denominator.
Patient Electronic Access	Provide Patient Access	Required	Up to 20	Numerator/Denominator.
	View, Download, or Transmit (VDT)	Not Required	Up to 10	Numerator/Denominator.
Patient-Specific Education	Patient-Specific Education	Not Required	Up to 10	Numerator/Denominator.
Secure Messaging	Secure Messaging	Not Required	Up to 10	Numerator/Denominator.
Health Information Exchange	Health Information Exchange	Required	Up to 20	Numerator/Denominator.
Medication Reconciliation	Medication Reconciliation	Not Required	Up to 10	Numerator/Denominator.
Public Health Reporting	Immunization Registry Reporting	Not Required	0 or 10	Yes/No Statement.
	Syndromic Surveillance Reporting	Not Required	0 or 5*	Yes/No Statement.
	Specialized Registry Reporting	Not Required	0 or 5*	Yes/No Statement.
Bonus up to 15%				
Report to one or more additional public health agencies or clinical data registries beyond those identified for the performance score.			5 bonus	Yes/No Statement.
Report improvement activities using CEHRT			10 bonus	Yes/No Statement.

*A MIPS eligible clinician who cannot fulfill the Immunization Registry Reporting measure may earn 5% for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10% under the performance score.

In the CY 2017 Quality Payment Program final rule (81 FR 77229 through 77237), we finalized the 2017 Advancing Care Information Transition Objectives and Measures for MIPS eligible clinicians using EHR technology certified to the 2014 Edition. We noted (81 FR 77229 that these objectives and measures have been adapted from the Modified Stage 2 objectives and measures finalized in the 2015 EHR Incentive Programs final rule (80 FR 62793 through 62825); however, we did not maintain the previously established thresholds for MIPS. For a more detailed discussion of the Modified Stage 2 Objectives and Measures, including explanatory material and defined terms, we refer readers to the 2015 EHR Incentive Programs final rule (80 FR 62793 through 62825). We are proposing to make several modifications identified and described below to the 2017 Advancing Care Information Transition Objectives and Measures for the advancing care information performance category of MIPS for the 2017 and 2018 performance periods. These modifications would not require changes to EHR technology that has been certified to the 2014 Edition.

We finalized the 2017 Advancing Care Information Transition Objectives and Measures only for the 2017 performance period because these objectives and measures are for MIPS eligible clinicians using EHR technology certified to the 2014 Edition. Because we are proposing in section II.C.6.f.(4) to continue to allow the use of EHR technology certified to the 2014 Edition in the 2018 performance period, we are also proposing to allow MIPS eligible clinicians to report the Advancing Care Information Transition Objectives and Measures in 2018.

Objective: Protect Patient Health Information.

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the

implementation of appropriate technical, administrative, and physical safeguards.

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing.

Objective: MIPS eligible clinicians must generate and transmit permissible prescriptions electronically.

E-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.
- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Objective: Patient Electronic Access.

Objective: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Proposed Modification to the Objective: We are proposing to modify this objective beginning with the 2017 performance period by removing the word ''electronic'' from the description of timely access as it was erroneously included in the final rule (81 FR 77228). It was our intention to align the objective with the objectives for Patient Specific Education and Patient Electronic Access adopted under modified Stage 2 in the 2015 EHR Incentive Programs final rule (80 FR 62809 and 80 FR 62815), which do not include the word ''electronic''. The word ''electronic'' was also not included in the certification specifications for the 2014 Edition, § 170.314(a)(15) (Patient-specific education resources) and § 170.314(e)(1) (View, download, and transmit to third party).

Provide Patient Access Measure: At least one patient seen by the MIPS eligible clinician during the performance period is provided timely access to view online, download, and transmit to a third party their health information subject to the MIPS eligible clinician's discretion to withhold certain information.

- *Denominator:* The number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party.

View, Download, Transmit (VDT) Measure: At least one patient seen by the MIPS eligible clinician during the performance period (or patient-authorized representative) views, downloads or transmits their health information to a third party during the performance period.

- *Denominator:* Number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period.

Objective: Patient-Specific Education.

Objective: The MIPS eligible clinician provides patients (or patient authorized representative) with timely electronic access to their health information and patient-specific education.

Proposed Change to the Objective: The MIPS eligible clinician uses clinically relevant information from CEHRT to identify patient-specific educational resources and provide those resources to the patient. We inadvertently finalized the description of the Patient Electronic Access objective for the Patient-Specific Education Objective, so that the Patient-Specific Education Objective had the wrong description. We are proposing to correct this error by adopting the description of the Patient-Specific Education Objective adopted under modified Stage 2 in the 2015 EHR Incentive Programs final rule (80 FR 62809 and 80 FR 62815). We are proposing this change would apply beginning with the performance period in 2017.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide access to those materials to at least one unique patient seen by the MIPS eligible clinician.

- *Denominator:* The number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator who were provided access to patient-specific educational resources using clinically relevant information identified from CEHRT during the performance period.

Objective: Secure Messaging.

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

Secure Messaging Measure: For at least one patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient authorized representative) during the performance period.

- *Denominator:* Number of unique patients seen by the MIPS eligible clinician during the performance period.
- *Numerator:* The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care clinicians into their EHR using the functions of CEHRT.

Proposed Change to the Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.

We inadvertently used the term ''health care clinician'' and are proposing to replace it with the more appropriate term ''health care provider''. We are proposing this change would

apply beginning with the performance period in 2017.

Health Information Exchange Measure: The MIPS eligible clinician that transitions or refers their patient to another setting of care or health care clinician (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving health care clinician for at least one transition of care or referral.

Proposed Change to the Measure: The MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving health care provider for at least one transition of care or referral.

This change reflects the change proposed to the Health Information Exchange objective replacing ''health care clinician'' with ''health care provider''. We are proposing this change would apply beginning with the performance period in 2017.

- *Denominator:* Number of transitions of care and referrals during the performance period for which the EP was the transferring or referring health care clinician.

Proposed Change to the Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring health care provider. This change reflects the change proposed to the Health Information Exchange Measure replacing ''health care clinician'' with ''health care provider''. We also inadvertently referred to the EP in the description and are replacing ''EP'' with ''MIPS eligible clinician''. We are proposing this change would apply beginning with the performance period in 2017.

- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Medication Reconciliation

Objective: Medication Reconciliation.

Proposed Objective: We are proposing to add a description of the Medication Reconciliation Objective beginning with the CY 2017 performance period, which we inadvertently omitted from the CY 2017 Quality Payment Program proposed and final rules, as follows:

Proposed Objective: The MIPS eligible clinician who receives a patient from another setting of care or provider of care or believes an encounter is relevant performs medication reconciliation. This description aligns with the objective adopted for Modified Stage 2 at 80 FR 62811.

Medication Reconciliation Measure: The MIPS eligible clinician performs medication reconciliation for at least one transition of care in which the patient is transitioned into the care of the MIPS eligible clinician.

- *Denominator:* Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.
- *Numerator:* The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list, Medication allergy list, and current problem list.

Proposed Modification to the Numerator

Proposed Numerator: The number of transitions of care or referrals in the denominator where medication reconciliation was performed.

We are proposing to modify the numerator by removing medication list, medication allergy list, and current problem list. These three criteria were adopted for Stage 3 (80 FR 62862) but not for Modified Stage 2 (80 FR 62811). We are proposing this change would apply beginning with the performance period in 2017.

Objective: Public Health Reporting.

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data.

Syndromic Surveillance Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data.

Specialized Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a specialized registry.

We invite public comments on these proposals.

(c) Exclusions

We are proposing to add exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives required for the base score. We propose these exclusions would apply beginning with the CY 2017 performance period. In the CY 2017 Quality Payment Program final rule (81 FR 77237 through 77238), we did not finalize any exclusions for the measures specified for the advancing care information performance category as we believe that the MIPS exclusion criteria and that the advancing care information performance category scoring methodology together accomplish the same end as the previously established exclusions for the majority of the advancing care information performance category measures. We further noted that it was not necessary to finalize the proposed exclusion for the Immunization Registry Reporting Measure because MIPS eligible clinicians have the flexibility to choose whether to report the measure because it is part of the performance score of the advancing care information performance category. However, we understand that many MIPS eligible clinicians may not achieve a base score because they cannot fulfill the measures associated with the Health Information Exchange objective in the base score because they seldom refer or transition patients, and we believe that the implementation burden of the objective is too high to require of those with only a small number of referrals or transitions. Similarly, we understand that many MIPS eligible clinicians do not often write prescriptions in their practice or lack prescribing authority, and thus could not meet the E-prescribing Measure and would also fail to earn a base score. As this was not our intention, we are proposing to establish exclusions for these measures, as described below.

Proposed Exclusion for the E-Prescribing Objective and Measure: In the CY 2017 Quality Payment Program final rule (81 FR 28237 through 28238), we established a policy that MIPS eligible clinicians who write fewer than 100 permissible prescriptions in a performance period may elect to report their numerator and denominator (if they have at least one permissible prescription for the numerator), or they may report a null value. This policy has confused MIPS eligible clinicians as a null value would appear to indicate a MIPS eligible clinician has failed the measure and thus not would not achieve a base score. We are proposing to change this policy beginning with the CY 2017 performance period and propose to establish an exclusion for the e-Prescribing Measure. MIPS eligible clinicians who wish to claim this exclusion would select ''yes'' to the exclusion and submit a null value for the measure, thereby fulfilling the requirement to report this measure as

part of the base score. It is important that a MIPS eligible clinician actually claims the exclusion if they wish to exclude the measure. If a MIPS eligible clinician does not claim the exclusion, they would fail the measure and not earn a base score or any score in the advancing care information performance category.

Advancing Care Information Objective and Measure.

Objective: Electronic Prescribing.

Objective: Generate and transmit permissible prescriptions electronically.

E-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.
- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Proposed Exclusion: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

2017 and 2018 Advancing Care Information Transition Objective and Measure

Objective: Electronic Prescribing.

Objective: MIPS eligible clinicians must generate and transmit permissible prescriptions electronically.

E-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.
- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Proposed Exclusion: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

Proposed Exclusion for the Health Information Exchange Objective and Measures: We are proposing to add exclusions for the measures associated with the Health Information Exchange Objective. Stakeholders have expressed concern through public comments on the CY 2017 Quality Payment Program proposed rule and other inquiries to us that some MIPS eligible clinicians are unable to meet the measures associated with the Health Information Exchange Objective, which are required for the base score, because they do not regularly refer or transition patients in the normal course of their practice. As we did not intend to disadvantage those MIPS eligible clinicians and prevent them from earning a base score, we are proposing the exclusions.

Advancing Care Information Objective and Measures

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care clinician into their EHR using the functions of CEHRT.

We note that we proposed above to replace ''health care clinician'' with ''health care provider''.

Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care clinician (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

We note that we proposed above to replace ''health care clinician'' with ''health care provider''.

- *Denominator:* Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.
- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Proposed Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Request/Accept Summary of Care Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

- *Denominator:* Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
- *Numerator:* Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the CEHRT.

Proposed Exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.

2017 and 2018 Advancing Care Information Transition Objective and Measures

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care clinicians into their EHR using the functions of CEHRT.

We note that we are proposing above to replace ''health care clinician'' with ''health care provider''.

Health Information Exchange Measure: The MIPS eligible clinician that transitions or refers their patient to another setting of care or health care clinician (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving health care clinician for at least one transition of care or referral.

We note that we are proposing above to replace ''health care clinician'' with ''health care provider''.

- *Denominator:* Number of transitions of care and referrals during the performance period for which the EP was the transferring or referring health care clinician.

We note that we are proposing above to replace ''health care clinician'' with ''health care provider''.

- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care

record was created using CEHRT and exchanged electronically.

Proposed Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

We are inviting public comment on these proposals.

(7) Additional Considerations

(a) 21st Century Cures Act

As we noted in the CY 2017 Quality Payment Program final rule (81 FR 77238), section 101(b)(1)(A) of the MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment at the end of CY 2018. Section 1848(a)(7) of the Act includes certain statutory exceptions to the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act. Specifically, section 1848(a)(7)(D) of the Act exempts hospital-based EPs from the application of the payment adjustment under section 1848(a)(7)(A) of the Act. In addition, section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment under section 1848(a)(7)(A) of the Act if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The last sentence of section 1848(a)(7)(B) of the Act also provides that in no case may an exemption be granted under subparagraph (B) for more than 5 years. The MACRA did not maintain these statutory exceptions for the advancing care information performance category of the MIPS. Thus, we had previously stated that the provisions under sections 1848(a)(7)(B) and (D) of the Act are limited to the meaningful use payment adjustment under section 1848(a)(7)(A) of the Act and do not apply in the context of the MIPS.

Following the publication of the CY 2017 Quality Payment Program final rule, the 21st Century Cures Act (Pub. L. 114–255) was enacted on December 13, 2016. Section 4002(b)(1)(B) of the 21st Century Cures Act amended section 1848(o)(2)(D) of the Act to state that the provisions of sections 1848(a)(7)(B) and (D) of the Act shall apply to assessments of MIPS eligible clinicians under section 1848(q) of the Act with respect to the performance category described in subsection (q)(2)(A)(iv) (the advancing care information performance category) in an appropriate manner which may be similar to the manner in which such provisions apply with respect to the meaningful use payment adjustment made under section 1848(a)(7)(A) of the Act. As a result of this legislative change, we believe that the general exceptions described under sections 1848(a)(7)(B) and (D) of the Act are applicable under the MIPS program. We include below proposals to implement these provisions as applied to assessments of MIPS eligible clinicians under section 1848(q) of the Act with respect to the advancing care information performance category.

(i) MIPS Eligible Clinicians Facing a Significant Hardship

In the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), we recognized that there may not be sufficient measures applicable and available under the advancing care information performance category to MIPS eligible clinicians facing a significant hardship, such as those who lack sufficient internet connectivity, face extreme and uncontrollable circumstances, lack control over the availability of CEHRT, or do not have face-to-face interactions with patients. We relied on section 1848(q)(5)(F) of the Act to establish a final policy to assign a zero percent weighting to the advancing care information performance category in the final score if there are not sufficient measures and activities applicable and available to MIPS eligible clinicians within the categories of significant hardship noted above (81 FR 77243). Additionally, under the final policy (81 FR 77243), we did not impose a limitation on the total number of MIPS payment years for which the advancing care information performance category could be weighted at zero percent, in contrast with the 5-year limitation on significant hardship exceptions under the Medicare EHR Incentive Program as required by section 1848(a)(7)(B) of the Act.

We are not proposing substantive changes to this policy; however, as a result of the changes in the law made by the 21st Century Cures Act discussed above, we will not rely on section 1848(q)(5)(F) of the Act and instead are proposing to use the authority in the last sentence of section 1848(o)(2)(D) of the Act for significant hardship exceptions under the advancing care information performance category under MIPS. Section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, states in part that the provisions of section 1848(a)(7)(B) of the Act shall apply to assessments of MIPS eligible clinicians with respect to the advancing care information performance category in an appropriate manner which may be similar to the manner in which such provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act. We would assign a zero percent weighting to the advancing care information performance category in the MIPS final score for a MIPS payment year for MIPS eligible clinicians who successfully demonstrate a significant hardship through the application process. We would use the same categories of significant hardship and application process as established in the CY 2017 Quality Payment Program final rule (81 FR 77240–77243). We would automatically reweight the advancing care information performance category to zero percent for a MIPS eligible clinician who lacks face-to-face patient interaction and is classified as a non-patient facing MIPS eligible clinician without requiring an application. If a MIPS eligible clinician submits an application for a significant hardship exception or is classified as a non-patient facing MIPS eligible clinician, but also reports on the measures specified for the advancing care information performance category, they would be scored on the advancing care information performance category like all other MIPS eligible clinicians, and the category would be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of the MIPS eligible clinician's score.

We believe this policy would be an appropriate application of the provisions of section 1848(a)(7)(B) of the Act to MIPS eligible clinicians and is similar to the manner in which those provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act. Under the Medicare EHR Incentive Program an approved hardship exception exempted an EP from the payment adjustment. We believe that weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category.

As required under section 1848(a)(7)(B) of the Act, eligible professionals were not granted significant hardship exceptions for the payment adjustments under the Medicare EHR Incentive Program for more than 5 years. We propose not to apply the 5-year limitation under section 1848(a)(7)(B) of the Act to significant hardship exceptions for the advancing care information performance category under MIPS. We believe this proposal is an appropriate application of the provisions of section 1848(a)(7)(B)

of the Act to MIPS eligible clinicians due to our desire to reduce clinician burden, promote the greatest level of participation in the MIPS program, and maintain consistency with the policies established in last year's final rule (81 FR 77243). In the Medicare EHR Incentive Program, we received many applications for significant hardship exceptions and approved most of them, which we believe indicates many eligible professionals were unable to or would have struggled to satisfy the requirements of meaningful use. We believe that there will be a continued need for significant hardship exceptions in order to provide clinicians with the necessary flexibility to participate in the MIPS program that best matches their available resources and circumstances, which may not change during a 5-year time period. For example, a clinician in an area without internet connectivity may continue to lack connectivity for more than 5 years. In addition, in the CY 2017 Quality Payment Program final rule (81 FR 77242 through 77243), we noted that we had received comments expressing appreciation that CMS moved away from the 5-year limitation to significant hardship exceptions.

We solicit comments on the proposed use of the authority provided in the 21st Century Cures Act in section 1848(o)(2)(D) of the Act as it relates to application of significant hardship exceptions under MIPS and the proposal not to apply a 5-year limit to such exceptions.

(ii) Significant Hardship Exception for MIPS Eligible Clinicians in Small Practices

Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to give consideration to the circumstances of small practices (consisting of 15 or fewer professionals) and practices located in rural areas and geographic HPSAs in establishing improvement activities under MIPS. In the CY 2017 Quality Payment Program final rule (81 FR 77187 through 77188), we finalized that for MIPS eligible clinicians and groups that are in small practices or located in rural areas, or geographic health professional shortage areas (HPSAs), to achieve full credit under the improvement activities category, one high-weighted or two medium-weighted improvement activities are required.

While there is no corresponding statutory provision for the advancing care information performance category, we believe that special consideration should also be available for MIPS eligible clinicians located in small practices. Through comments received on the CY 2017 Quality Payment Program proposed rule (81 FR 28161–28586), we heard many concerns about the impact of MIPS on eligible clinicians in small practices. Some commenters stated that there was not a meaningful exclusion for small practices that cannot afford the upfront investments (including investments in EHR technology) (81 FR 77066). Many noted there are still many small practices that have not adopted EHRs due to the administrative and financial burden. Some expressed concern that small group and solo practices would be driven out of business because of the potential negative payment adjustments under MIPS (81 FR 77055). A few commenters were concerned about the impact of MACRA on small practices and asked CMS to remain sensitive to this concern and offer special opportunities for MIPS eligible clinicians in areas threatened by access problems (81 FR 77055).

Based on these concerns, we are proposing a significant hardship exception for the advancing care information performance category for MIPS eligible clinicians who are in small practices, under the authority in section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act (see discussion of the statutory authority for significant hardship exceptions in section II.C.6.f.(7)(ii). We are proposing that this hardship exception would be available to MIPS eligible clinicians in small practices as defined under § 414.1305 (15 or fewer clinicians and solo practitioners). We are proposing in section II.C.1.e. of this proposed rule, that CMS would make eligibility determinations regarding the size of small practices for performance periods occurring in 2018 and future years. We are proposing to reweight the advancing care information performance category to zero percent of the MIPS final score for MIPS eligible clinicians who qualify for this hardship exception. We are proposing this exception would be available beginning with the 2018 performance period and 2020 MIPS payment year. We are proposing a MIPS eligible clinician seeking to qualify for this exception would submit an application in the form and manner specified by us by December 31st of the performance period or a later date specified by us. We are also proposing MIPS eligible clinicians seeking this exception must demonstrate in the application that there are overwhelming barriers that prevent the MIPS eligible clinician from complying with the requirements for the advancing care information performance category. In accordance with section 1848(a)(7)(B) of the Act, the exception would be subject to annual renewal. Under our proposal in section II.C.6.f.(7)(a), the 5-year limitation under section 1848(a)(7)(B) of the Act would not apply to this significant hardship exception for MIPS eligible clinicians in small practices.

We believe that applying the significant hardship exception in this way would be appropriate given the challenges small practices face as described by the commenters. In addition, we believe this application would be similar to the manner in which the exception applies with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act because weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category.

While we would be making this significant hardship exception available to small practices in particular, we are considering whether other categories or types of clinicians might similarly require an exception. We solicit comment on what those categories or types are, why such an exception is required, and any data available to support the necessity of the exception. We note that supporting data would be particularly helpful to our consideration of whether any additional exceptions would be appropriate.

We are seeking comments on these proposals.

(iii) Hospital-Based MIPS Eligible Clinicians

In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240), we defined a hospital-based MIPS eligible clinician under § 414.1305 as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS 21), on-campus outpatient hospital (POS 22), or emergency room (POS 23) setting, based on claims for a period prior to the performance period as specified by CMS. We intend to use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we will use a 12-month period as close as practicable to this time period. We discussed our assumption that MIPS eligible clinicians who are determined hospital-based do not have

sufficient advancing care information measures applicable to them, and we established a policy to reweight the advancing care information performance category to zero percent of the MIPS final score for the MIPS payment year in accordance with section 1848(q)(5)(F) of the Act (81 FR 77240).

We are not proposing substantive changes to this policy; however, as a result of the changes in the law made by the 21st Century Cures Act discussed above, we will not rely on section 1848(q)(5)(F) of the Act and instead are proposing to use the authority in the last sentence of section 1848(o)(2)(D) of the Act for exceptions for hospital-based MIPS eligible clinicians under the advancing care information performance category. Section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, states in part that the provisions of section 1848(a)(7)(D) of the Act shall apply to assessments of MIPS eligible clinicians with respect to the advancing care information performance category in an appropriate manner which may be similar to the manner in which such provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act. We would assign a zero percent weighting to the advancing care information performance category in the MIPS final score for a MIPS payment year for hospital-based MIPS eligible clinicians as previously defined. A hospital-based MIPS eligible clinician would have the option to report the advancing care information measures for the performance period for the MIPS payment year for which they are determined hospital-based. However, if a MIPS eligible clinician who is determined hospital-based chooses to report on the advancing care information measures, they would be scored on the advancing care information performance category like all other MIPS eligible clinicians, and the category would be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their score.

We believe this policy would be an appropriate application of the provisions of section 1848(a)(7)(D) of the Act to MIPS eligible clinicians and is similar to the manner in which those provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act. Under the Medicare EHR Incentive Program an approved hardship exception exempted an EP from the payment adjustment. We believe that weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category.

We propose to amend § 414.1380(c)(1) and (2) of the regulation text to reflect this proposal.

We request comments on the proposed use of the authority provided in the 21st Century Cures Act in section 1848(o)(2)(D) of the Act as it relates to hospital-based MIPS eligible clinicians.

(iv) Ambulatory Surgical Center (ASC)—Based MIPS Eligible Clinicians

Section 16003 of the 21st Century Cures Act amended section 1848(a)(7)(D) of the Act to provide that no payment adjustment may be made under section 1848(a)(7)(A) of the Act for 2017 and 2018 in the case of an eligible professional who furnishes substantially all of his or her covered professional services in an ambulatory surgical center (ASC). Section 1848(a)(7)(D)(iii) of the Act provides that determinations of whether an eligible professional is ASC-based may be made based on the site of service as defined by the Secretary or an attestation, but shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services. Section 1848(a)(7)(D)(iv) of the Act provides that the ASC-based exception shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice and comment rulemaking, that CEHRT applicable to the ASC setting is available.

Under section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, the ASC-based provisions of section 1848(a)(7)(D) of the Act shall apply to assessments of MIPS eligible clinicians under section 1848(q) of the Act with respect to the advancing care information performance category in an appropriate manner which may be similar to the manner in which such provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act. We believe our proposals set forth below for ASC-based MIPS eligible clinicians are an appropriate application of the provisions of section 1848(a)(7)(D) of the Act to MIPS eligible clinicians. Under the Medicare EHR Incentive Program an approved hardship exception exempted an EP from the payment adjustment. We believe that weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category.

To align with our hospital-based MIPS eligible clinician policy, we are proposing to define at § 414.1305 an ASC-based MIPS eligible clinician as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) code 24 used in the HIPAA standard transaction based on claims for a period prior to the performance period as specified by us. We request comments on this proposal and solicit comments as to whether other POS codes should be used to identify a MIPS eligible clinician's ASC-based status or if an alternative methodology should be used. We note that the ASC-based determination will be made independent of the hospital-based determination.

To determine a MIPS eligible clinician's ASC-based status, we are proposing to use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period. For example, for the 2018 performance period (2020 MIPS payment year), we would use the data available at the end of October 2017 for Medicare claims with dates of service between September 1, 2016 through August 31, 2017, to determine whether a MIPS eligible clinician is considered ASC-based under our proposed definition. We are proposing this timeline to allow us to notify MIPS eligible clinicians of their ASC-based status prior to the start of the performance period and to align with the hospital-based MIPS eligible clinician determination period. For the 2019 MIPS payment year, we would not be able to notify MIPS eligible clinicians of their ASC-based status until after the final rule is published, which we anticipate would be later in 2017. We expect that we would provide this notification through *QPP.cms.gov*.

For MIPS eligible clinicians who we determine are ASC-based, we propose to assign a zero percent weighting to the advancing care information performance category in the MIPS final score for the MIPS payment year. However, if a MIPS eligible clinician who is determined ASC-based chooses to report on the advancing care information measures for the performance period for the MIPS payment year for which they are determined ASC-based, we propose they would be scored on the advancing care information performance category like

all other MIPS eligible clinicians, and the performance category would be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their advancing care information performance category score.

We are proposing these ASC-based policies would apply beginning with the 2017 performance period/2019 MIPS payment year.

We propose to amend § 414.1380(c)(1) and (2) of the regulation text to reflect these proposals.

We request comments on these proposals.

(v) Exception for MIPS Eligible Clinicians Using Decertified EHR Technology

Section 4002(b)(1)(A) of the 21st Century Cures Act amended section 1848(a)(7)(B) of the Act to provide that the Secretary shall exempt an eligible professional from the application of the payment adjustment under section 1848(a)(7)(A) of the Act with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the CEHRT used by such professional has been decertified under ONC's Health IT Certification Program. Section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, states in part that the provisions of section 1848(a)(7)(B) of the Act shall apply to assessments of MIPS eligible clinicians with respect to the advancing care information performance category in an appropriate manner which may be similar to the manner in which such provisions apply with respect to the payment adjustment made under section 1848(a)(7)(A) of the Act.

We are proposing that a MIPS eligible clinician may demonstrate through an application process that reporting on the measures specified for the advancing care information performance category is not possible because the CEHRT used by the MIPS eligible clinician has been decertified under ONC's Health IT Certification Program. We are proposing that if the MIPS eligible clinician's demonstration is successful and an exception is granted, we would assign a zero percent weighting to the advancing care information performance category in the MIPS final score for the MIPS payment year. In accordance with section 1848(a)(7)(B) of the Act, the exception would be subject to annual renewal, and in no case may a MIPS eligible clinician be granted an exception for more than 5 years. We are proposing this exception would be available beginning with the CY 2018 performance period and the 2020 MIPS payment year.

We are proposing that a MIPS eligible clinician may qualify for this exception if their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year. We believe that this timeframe is appropriate because the loss of certification may prevent a MIPS eligible clinician from reporting for the advancing care information performance category because it will require that the MIPS eligible clinician switch to an alternate CEHRT, a process that we believe may take up to 2 years. For example, for the 2020 MIPS payment year, if the MIPS eligible clinician's EHR technology was decertified during the CY 2018 performance period or during CY 2017, the MIPS eligible clinician may qualify for this exception. In addition, we are proposing that the MIPS eligible clinician must demonstrate in their application and through supporting documentation if available that the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. We are proposing a MIPS eligible clinician seeking to qualify for this exception would submit an application in the form and manner specified by us by December 31st of the performance period, or a later date specified by us.

We believe that applying the exception in this way is an appropriate application of the provisions of section 1848(a)(7)(B) of the Act to MIPS eligible clinicians given that weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category. Under the Medicare EHR Incentive Program an approved hardship exception exempted an EP from the payment adjustment. We believe that weighting the advancing care information performance category to zero percent is similar in effect to an exemption from the requirements of that performance category.

The ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule (''EOA final rule'') (81 FR 72404), effective December 19, 2016, created a regulatory framework for the ONC's direct review of health information technology (health IT) certified under the ONC Health IT Certification Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and/or terminating certifications issued to certified health IT. Prior to the EOA final rule, ONC-Authorized Certification Bodies (ONC–ACBs) had the only authority to terminate or revoke certification of health IT under the program, which they used on previous occasions. On September 23, 2015, we posted an FAQ discussing the requirements for using a decertified CEHRT.[3]

Once all administrative processes, if any, are complete, then notice of a ''termination of certification'' is listed on the of the Certified Health IT Product List (CPHL) Web page.[4] As appropriate, ONC will also publicize the termination of certification of health IT through other communication channels (for example, ONC list serv(s)). Further, when ONC terminates the certification of a health IT product, the health IT developer is required to notify all potentially affected customers in a timely manner.

We further note that in comparison to termination actions taken by ONC and ONC–ACBs, a health IT developer may voluntarily withdraw a certification that is in good standing under the ONC Health IT Certification Program. A voluntary withdrawal may be the result of the health IT developer going out of business, the developer no longer supporting the product, or for other reasons that are not in response to ONC–ACB surveillance, ONC direct review, or a finding of non-conformity by ONC or an ONC–ACB.[5] In such instances, ONC will list these products on the ''Inactive Certificates'' [6] Web page of the CHPL.

We propose to amend § 414.1380(c)(1) and (2) of the regulation text to reflect these proposals. We are seeking comments on these proposals.

(b) Hospital-Based MIPS Eligible Clinicians

In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240, we defined a hospital-based MIPS eligible clinician as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of services identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS 21), on campus outpatient hospital

[3] *https://questions.cms.gov/faq.php?isDept=0&search=decertify&searchType=keyword&submitSearch=1&id=5005.*

[4] The list is available at *https://chpl.healthit.gov/#/decertifications/products.*

[5] For further descriptions of certification statuses, please consult the CHPL Public User Guide.

[6] The ''Inactive Certificates'' Web page is available at *https://chpl.healthit.gov/#/decertifications/inactive.*

(POS 22) or emergency room (POS 23) setting, based on claims for a period prior to the performance period as specified by CMS.

We are proposing to modify our policy to include covered professional services furnished by MIPS eligible clinicians in an off-campus-outpatient hospital (POS 19) in the definition of hospital-based MIPS eligible clinician. POS 19 was developed in 2015 in order to capture the numerous physicians that are paid for a portion of their services in an ''off campus-outpatient hospital'' versus an on campus-outpatient hospital, (POS 22). We also believe that these MIPS eligible clinicians would not typically have control of the development and maintenance of their EHR systems, just like those who bill using POS 22. We propose to add POS 19 to our existing definition of a hospital-based MIPS eligible clinician beginning with the performance period in 2018.

We invite comment on this proposal.

(c) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In the CY 2017 Quality Payment Program final rule (81 FR 77243–77244), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians are not eligible to participate in the Medicare or Medicaid EHR Incentive Program, we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information performance category. We established a policy under section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the advancing care information performance category. We encouraged all NPs, PAs, CRNAs, and CNSs to report on these measures to the extent they are applicable and available, however, we understand that some NPs, PAs, CRNAs, and CNSs may choose to accept a weight of zero for this performance category if they are unable to fully report the advancing care information measures. These MIPS eligible clinicians may choose to submit advancing care information measures should they determine that these measures are applicable and available to them; however, we noted that if they choose to report, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their advancing care information performance category score.

We stated that this approach is appropriate for the first MIPS performance period based on the payment consequences associated with reporting, the fact that many of these types of MIPS eligible clinicians may lack experience with EHR use, and our current uncertainty as to whether we have adopted sufficient measures that are applicable and available to these types of MIPS eligible clinicians. We noted that we would use the first MIPS performance period to further evaluate the participation of these MIPS eligible clinicians in the advancing care information performance category and would consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. At this time we have no additional information because the first MIPS performance period is currently underway, and thus we propose the same policy for NPs, PAs, CRNAs, and CNSs for the 2018 performance period as well. We still intend to evaluate the participation of these MIPS eligible clinicians in the advancing care information performance category for 2017 and expect to adopt measures applicable and available to them in subsequent years.

We are seeking comment on how the advancing care information performance category could be applied to NPs, PAs, CRNAs, and CNSs in future years of MIPS, and the types of measures that would be applicable and available to these types of MIPS eligible clinicians. In addition, through the Call for Measures Process we are seeking new measures that may be more broadly applicable to these additional types of MIPS eligible clinicians in future program years. For more information on the Call for Measures, see *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallForMeasures.html*.

We are inviting public comment on these proposals.

(d) Scoring for MIPS Eligible Clinicians in Group Practices

In any of the situations described in the sections above, we would assign a zero percent weighting to the advancing care information performance category in the MIPS final score for the MIPS payment year if the MIPS eligible clinician meets certain specified requirements for this weighting. We noted that these MIPS eligible clinicians may choose to submit advancing care information measures; however, if they choose to report, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their advancing care information performance category score. This policy includes MIPS eligible clinicians choosing to report as part of a group practice or part of a virtual group.

Group practices as defined at § 414.1310(e)(1) are required to aggregate their performance data across the TIN in order for their performance to be assessed as a group (81 FR 77058). Additionally, groups that elect to have their performance assessed as a group will be assessed as a group across all four MIPS performance categories. By reporting as part of a group practice, MIPS eligible clinicians are subscribing to the data reporting and scoring requirements of the group practice. We note that the data submission criteria for groups reporting advancing care information performance category described in the CY 2017 Quality Payment Program final rule (81 FR 77215) state that group data should be aggregated for all MIPS eligible clinicians within the group practice. This includes those MIPS eligible clinicians who may qualify for a zero percent weighting of the advancing care information performance category due to the circumstances as described above, such as a significant hardship or other type of exception, hospital-based or ASC-based status, or certain types of non-physician practitioners (NPs, PAs, CNSs, and CRNAs). If these MIPS eligible clinicians report as part of a group practice or virtual group, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of the group practice's advancing care information performance category score.

(e) Timeline for Submission of Reweighting Applications

In the CY 2017 Quality Payment Program final rule (81 FR77240–77243), we established the timeline for the submission of applications to reweight the advancing care information performance category in the MIPS final score to align with the data submission timeline for MIPS. We established that all applications for reweighting the advancing care information performance category be submitted by the MIPS eligible clinician or designated group representative in the form and manner specified by us. All applications may be submitted on a rolling basis, but must be received by us no later than the close of the submission period for the relevant performance period, or a later date specified by us. An application would need to be submitted annually to be considered for reweighting each year.

The Quality Payment Program Exception Application will be used to apply for the following exceptions: Insufficient Internet Connectivity; Extreme and Uncontrollable Circumstances; Lack of Control over the Availability of CEHRT; Decertification of CEHRT; and Small Practice.

We are proposing to change the submission deadline for the application as we believe that aligning the data submission deadline with the reweighting application deadline could disadvantages MIPS eligible clinicians. We are proposing to change the submission deadline for the CY 2017 performance period to December 31, 2017, or a later date specified by us. We believe this change would help MIPS eligible clinicians by allowing them to learn whether their application is approved prior to the data submission deadline for the CY 2017 performance period, March 31, 2018. We plan to have the application available in mid-2017. We encourage MIPS eligible clinicians to apply early as we expect to process the applications on a rolling basis. We note that if a MIPS eligible clinician submits data for the advancing care information category after an application has been submitted, the data would be scored, the application would be considered voided and the advancing care information performance category would not be reweighted.

We further propose that the submission deadline for the 2018 performance period will be December 31, 2018, or a later date as specified by us. We believe this would help MIPS eligible clinicians by allowing them to learn whether their application is approved prior to the data submission deadline for the CY 2018 performance period, March 31, 2019.

We request comments on these proposals.

g. APM Scoring Standard for MIPS Eligible Clinicians in MIPS APMs

(1) Overview

Under section 1848(q)(1)(C)(ii)(1) of the Act, Qualifying APM Participants (QPs) are not MIPS eligible clinicians and are thus excluded from MIPS reporting requirements and payment adjustments. Similarly, under section 1848(q)(1)(c)(ii)(II) of the Act, Partial Qualifying APM Participants (Partial QPs) are also not MIPS eligible clinicians unless they opt to report and be scored under MIPS. All other eligible clinicians, including those participating in MIPS APMs, are MIPS eligible clinicians and subject to MIPS reporting requirements and payment adjustments unless they are excluded on another basis such as being newly enrolled in Medicare or not exceeding the low volume threshold.

In the CY 2017 Quality Payment Program final rule (81 FR 77246–77269, 77543), we finalized the APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by minimizing the need for them to make duplicative data submissions for both MIPS and their respective APMs. We also sought to ensure that eligible clinicians in APM Entities that participate in certain types of APMs that assess their participants on quality and cost are assessed as consistently as possible across MIPS and their respective APMs. Given that many APMs already assess their participants on cost and quality of care and require engagement in certain improvement activities, we believe that without the APM scoring standard, misalignments could be quite common between the evaluation of performance under the terms of the APM and evaluation of performance on measures and activities under MIPS.

In the CY 2017 Quality Payment Program final rule (81 FR 77249), we identified the types of APMs for which the APM scoring standard would apply as MIPS APMs. We finalized that to be a MIPS APM, an APM must satisfy the following criteria: (1) APM Entities participate in the APM under an agreement with CMS or by law or regulation; (2) the APM requires that APM Entities include at least one MIPS eligible clinician on a Participation List; and (3) the APM bases payment incentives on performance (either at the APM Entity or eligible clinician level) on cost/utilization and quality measures. We specified that we will post the list of MIPS APMs prior to the first day of the MIPS performance year for each year (81 FR 77250). We finalized in the regulation at § 414.1370(b) that for a new APM to be a MIPS APM, its first performance year must start on or before the first day of the MIPS performance year. A list of MIPS APMs is available at *www.qpp.cms.gov*.

We established in the regulation at § 414.1370(c) that the MIPS performance year under § 414.1320 of the regulations applies for the APM scoring standard.

We finalized that under section § 414.1370(f) of our regulations on the APM scoring standard, MIPS eligible clinicians will be scored at the APM Entity group level and each eligible clinician will receive the APM Entity group's final score. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity. The MIPS final score is comprised of the four MIPS performance category scores, as described in our regulation at § 414.1370(g): quality, cost, improvement activities, and advancing care information. Both the Medicare Shared Savings Program and Next Generation ACO Model are MIPS APMs for the CY 2017 performance year. For these two MIPS APMs, in accordance with our regulation at § 414.1370(h), the MIPS performance category scores are weighted as follows: Quality at 50 percent; cost at zero percent; improvement activities at 20 percent; and advancing care information at 30 percent of the final score. For all other MIPS APMs for the CY 2017 performance year, quality and cost are each weighted at zero percent, improvement activities at 25 percent, and advancing care information at 75 percent of the final score.

As explained in the following sections, we propose to: Add an APM participant assessment date for full TIN APMs; add the CAHPS for ACOs survey to the Shared Savings Program and Next Generation ACO quality measures included for scoring under the MIPS APM quality performance category; define Other MIPS APMs; and add scoring for quality improvement to the MIPS APM quality performance category for MIPS APMs beginning in 2018. We also propose a Quality Payment Program 2018 performance year quality scoring methodology for Other MIPS APMs, and describe the scoring methodology for quality improvement for Other MIPS APMs as applicable.

In reviewing these proposals, we remind readers that the APM scoring

standard is built upon the generally applicable MIPS scoring standard, but provides for special policies to address the unique circumstances of MIPS eligible clinicians who are in APM Entities participating in MIPS APMs. For the cost, improvement activities, and advancing care information performance categories, unless a separate policy has been established or is being proposed for the APM scoring standard, the generally applicable MIPS policies would be applicable. Additionally, unless we include a proposal to adopt a unique policy for the APM scoring standard, we propose to adopt the same generally applicable MIPS policies proposed elsewhere in this proposed rule, and would treat the APM Entity group as the group for purposes of MIPS. For the quality performance category, however, the APM scoring standard we propose is presented as a separate, unique standard, and therefore generally applicable MIPS policies would not be applied to the quality performance category under the APM scoring standard unless specifically stated. We seek comment on whether there may be potential conflicts or inconsistencies between the generally applicable MIPS policies and those under the APM scoring standard, particularly where these could impact our goals to reduce duplicative and potentially incongruous reporting requirements and performance evaluations that could undermine our ability to test or evaluate MIPS APMs, or whether certain generally applicable MIPS policies should be made explicitly applicable to the APM scoring standard.

(2) Assessment Dates for Inclusion of MIPS Eligible Clinicians in APM Entity Groups Under the APM Scoring Standard

In the CY 2017 Quality Payment Program final rule, we specified in the regulation at § 414.1370(e) that the APM Entity group for purposes of scoring under the APM scoring standard is determined in the manner prescribed at § 414.1425(b)(1), which provides that eligible clinicians who are on a Participation List on at least one of three dates (March 31, June 30, and August 31) would be considered part of the APM Entity group. Under these regulations, MIPS eligible clinicians who are not on a Participation List on one of these three assessment dates are not scored under the APM scoring standard. Instead, they would need to submit data to MIPS through one of the MIPS data submission mechanisms and their performance would be assessed either as individual MIPS eligible clinicians or as a group according to the generally applicable MIPS reporting and scoring criteria.

We will continue to use the three assessment dates of March 31, June 30, and August 31 to identify MIPS eligible clinicians who are on an APM Entity's Participation List and determine the APM Entity group that is used for purposes of the APM scoring standard. Beginning in the 2018 performance year, we propose to add a fourth assessment date of December 31 to identify those MIPS eligible clinicians who participate in a full TIN APM. We propose to define full TIN APM at § 414.1305 to mean an APM where participation is determined at the TIN level, and all eligible clinicians who have assigned their billing rights to a participating TIN are therefore participating in the APM. An example of a full TIN APM is the Shared Savings Program which requires all individuals and entities that have reassigned their right to receive Medicare payment to the TIN of an ACO participant to participate in the ACO and comply with the requirements of the Shared Savings Program.

If an eligible clinician elects to reassign their billing rights to a TIN participating in a full TIN APM, the eligible clinician is necessarily participating in the full TIN APM. We propose to add this fourth date of December 31 only for eligible clinicians in a full TIN APM, and only for purposes of applying the APM scoring standard. We are not proposing to use this additional assessment date of December 31 for purposes of QP determinations. Therefore, we propose to amend § 414.1370(e) to identify the four assessment dates that would be used to identify the APM Entity group for purposes of the APM scoring standard, and to specify that the December 31 date would be used only to identify eligible clinicians on the APM Entity's Participation List for a MIPS APM that is a full TIN APM in order to add them to the APM Entity group that is scored under the APM scoring standard.

We propose to use this fourth assessment date of December 31 to extend the APM scoring standard to only those MIPS eligible clinicians participating in MIPS APMs that are full TIN APMs, ensuring that an eligible clinician who joins the full TIN APM late in the performance year would be scored under the APM scoring standard. We considered proposing to use the fourth assessment date more broadly for all MIPS APMs. However, we believe that this approach would have allowed MIPS eligible clinicians to inappropriately leverage the fourth assessment date to avoid reporting and scoring under the generally applicable MIPS scoring standard when they were part of the MIPS APM for only a very limited portion of the performance year. That is, for MIPS APMs that allow split TIN participation, it would be possible for eligible clinicians to briefly join a MIPS APM principally in order to benefit from the APM scoring standard, despite having limited opportunity to contribute to the APM Entity's performance in the MIPS APM. In contrast, we believe MIPS eligible clinicians would be less likely to join a full TIN APM principally to avail themselves of the APM scoring standard, since doing so would require either that the entire TIN join the MIPS APM or the administratively burdensome act of the eligible clinician reassigning their billing rights to the TIN of an entity participating in the full TIN APM.

We will continue to use only the three dates of March 31, June 30, and August 31 to determine, based on Participation Lists, the MIPS eligible clinicians who participate in MIPS APMs that are not full TIN APMs. We seek comment on the proposed addition of the fourth date of December 31 to assess Participation Lists to identify MIPS eligible clinicians who participate in MIPS APMs that are full TIN APMs for purposes of the APM scoring standard.

(3) Calculating MIPS APM Performance Category Scores

In the CY 2017 Quality Payment Program final rule, we established a scoring standard for MIPS eligible clinicians participating in MIPS APMs to reduce participant reporting burden by reducing the need for eligible clinicians participating in these types of APMs to make duplicative data submissions for both MIPS and their respective APMs (81 FR 77246 through 77271). In accordance with section 1848(q)(1)(D)(i) of the Act, we proposed to assess the performance of a group of MIPS eligible clinicians in an APM Entity that participates in one or more MIPS APMs based on their collective performance as an APM Entity group, as defined at § 414.1305.

In addition to reducing reporting burden, we sought to ensure that eligible clinicians in MIPS APMs are not assessed in multiple ways on the same performance activities. Depending on the terms of the particular MIPS APM, we believe that misalignments could be common between the evaluation of performance on quality and cost under MIPS versus under the terms of the APM. We believe requiring eligible clinicians in MIPS APMs to submit data, be scored on measures, and be subject

to payment adjustments that are not aligned between MIPS and an APM could potentially undermine the validity of testing or performance evaluation under the APM. We also believe imposition of MIPS reporting requirements would result in reporting activity that provides little or no added value to the assessment of eligible clinicians, and could confuse eligible clinicians as to which CMS incentives should take priority over others in designing and implementing care improvement activities.

(a) Cost Performance Category

In the CY 2017 Quality Payment Program final rule, for MIPS eligible clinicians participating in MIPS APMs, we used our authority to waive requirements under the Medicare statute to reduce the scoring weight for the cost performance category to zero (81 FR 77258, 77262, and 77266). We did this for MIPS APMs authorized under section 1115A of the Act using our authority under section 1115A(d)(1) of the Act to waive the requirement under section 1848(q)(5)(E)(i)(II) of the Act that specifies the scoring weight for the cost performance category. Having reduced the cost performance category weight to zero, we further used our authority under section 1115A(d)(1) of the Act to waive the requirements under sections 1848(q)(2)(B)(ii) and 1848(q)(2)(A)(ii) of the Act to specify and use, respectively, cost measures in calculating the MIPS final score for MIPS eligible clinicians participating in Other MIPS APMs (81 FR 77261 through 77262 and 77265 through 77266). Similarly, for MIPS eligible clinicians participating in the Medicare Shared Savings Program, we used our authority under section 1899(f) of the Act to waive the same requirements of section 1848 of the Act for the MIPS cost performance category (81 FR 77257 through 77258). We finalized this policy because: (1) APM Entity groups are already subject to cost and utilization performance assessment under the MIPS APMs; (2) MIPS APMs usually measure cost in terms of total cost of care, which is a broader accountability standard that inherently encompasses the purpose of the claims-based measures that have relatively narrow clinical scopes, and MIPS APMs that do not measure cost in terms of total cost of care may depart entirely from MIPS measures; and (3) the beneficiary attribution methodologies differ for measuring cost under APMs and MIPS, leading to an unpredictable degree of overlap (for eligible clinicians and for CMS) between the sets of beneficiaries for which eligible clinicians would be responsible that would vary based on the unique APM Entity characteristics such as which and how many eligible clinicians comprise an APM Entity group. We believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population, measurement of the population identified through the APM must take priority in order to ensure that the goals and the model evaluation associated with the APM are as clear and free of confounding factors as possible. The potential for different, conflicting results across APMs and MIPS assessments may create uncertainty for MIPS eligible clinicians who are attempting to strategically transform their respective practices and succeed under the terms of the APM. We are not proposing changes to these policies.

We welcome comment on our proposal to continue to waive the weighting of the cost performance category for the 2020 payment year forward.

(i) Measuring Improvement in the Cost Performance Category

In setting performance standards with respect to measures and activities in each MIPS performance category, section 1848(q)(3)(B) of the Act requires us to consider, historical performance standards, improvement, and the opportunity for continued improvement. Section 1848(q)(5)(D)(i)(I) requires us to introduce the measurement of improvement into performance scores in the cost performance category for MIPS eligible clinicians for the 2020 MIPS Payment Year if data sufficient to measure improvement are available. Section 1848(q)(5)(D)(i)(II) permits us to take into account improvement in the case of performance scores in other performance categories. Given that we have in effect waivers of the scoring weight for the cost performance category, and of the requirement to specify and use cost measures in calculating the MIPS final score for MIPS eligible clinicians participating in MIPS APMs, and for the same reasons that we initially waived those requirements, we propose to use our authority under section 1115A(d)(1) of the Act for MIPS APMs authorized under section 1115A of the Act and under section 1899(f) of the Act for MIPS APMs under the Medicare Shared Savings Program, to waive the requirement under section 1848(q)(5)(D)(i)(I) of the Act to take improvement into account for performance scores in the cost performance category beginning with the 2018 MIPS performance year.

We seek comment on this proposal.

(b) Quality Performance Category

(i) Web Interface Reporters: Shared Savings Program and Next Generation ACO Model

(A) Quality Measures

We finalized in the CY 2017 Quality Payment Program final rule that under the APM scoring standard, participants in the Shared Savings Program and Next Generation ACO Model would be assessed for the purposes of generating a MIPS APM quality performance category score based exclusively on quality measures submitted using the CMS Web Interface (81 FR 77256 and 77261). In the CY 2017 Quality Payment Program final rule, we recognized that ACOs in both the Shared Savings Program and Next Generation ACO Model use the CMS Web Interface to submit data on quality measures, and that the measures they would report were also MIPS measures for 2017. For the Shared Savings Program and the Next Generation ACO Model, we finalized a policy to use quality measures and data submitted by the participant ACOs to the CMS Web Interface (as required under the rules for these initiatives) and MIPS benchmarks for these measures to score quality for MIPS eligible clinicians in these MIPS APMs at the APM Entity level (81 FR 77256, 77261). For these MIPS APMs, which we refer to as Web Interface reporters going forward, we established that quality performance data that are not submitted to the CMS Web Interface, for example the CAHPS for ACOs survey and claims-based measures, will not be included in the MIPS APM quality performance category score for 2017.

(aa) Addition of New Measures

For the Shared Savings Program and Next Generation ACO Model, we propose to score the CAHPS for ACOs survey, in addition to the CMS Web Interface measures that are used to calculate the MIPS APM quality performance category score for the Shared Savings Program and Next Generation ACO Model, beginning in the 2018 performance year. The CAHPS for ACOs survey is already required in the Shared Savings Program and Next Generation ACO Model, and including the CAHPS for ACOs survey would better align the measures on which participants in these MIPS APMs are assessed under the APM scoring standard with the measures used to

assess participants' quality performance under the APM.

We did not initially propose to include the CAHPS for ACOs survey as part of the MIPS APM quality performance category scoring for the Shared Savings Program and Next Generation ACO Model because we believed that the CAHPS for ACOs survey would not be collected and scored in time to produce a MIPS quality performance category score. However, operational efficiencies have recently been introduced that have made it possible to score the CAHPS for ACOs survey on the same timeline as the CAHPS for MIPS survey. Under our proposal, the CAHPS for ACOs survey would be added to the total number of quality performance category measures available for scoring in these MIPS APMs.

While the CAHPS for ACOs survey is new to MIPS APM scoring, the CG–CAHPS survey upon which it is based is also the basis for the CAHPS for MIPS survey, which was included on the MIPS final list for the 2017 performance year. For a further discussion of the CAHPS for ACOs survey, and the way it will be scored, we refer readers to II.C.6.b.(3)(a)(ii) of this proposed rule, which describes the identical CAHPS for MIPS survey and its scoring method that will be used for MIPS in the 2018 performance year. We note that although each question in the CAHPS for ACOs survey can also be found in the CAHPS for MIPS survey, the CAHPS for ACOs survey will have one fewer survey question the SSM entitled ''Between Visit Communication'', which has never been a scored measure with the Medicare Shared Savings Program CAHPS for ACOs Survey and which we believe to be inappropriate for use by ACOs.

TABLE 10—WEB INTERFACE REPORTERS: SHARED SAVINGS PROGRAM AND NEXT GENERATION ACO MODEL NEW MEASURE

Measure name	NQF/quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
CAHPS for ACOs	N/A	Patient/Caregiver Experience.	Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (SSP) and Next Generation ACOs ask consumers about their experiences with health care. The CAHPS for ACOs Survey is collected from a sample of beneficiaries who get the majority of their care from an ACO, and the questions address care received from a named clinician within the ACO. Survey measures include: —Getting Timely Care, Appointments, and Information. —How Well Your Providers Communicate. —Patients' Rating of Providers. —Access to Specialists. —Health Promotion and Education. —Shared Decision Making. —Health Status/Functional Status. —Stewardship of Patient Resources.	Agency for Healthcare Research and Quality (AHRQ)

(B) Calculating Quality Scores

We refer readers to section II.C.7.a.(1)(h)(ii) of this proposed rule for our summary of finalized policies and proposed changes related to calculating the MIPS quality performance category percent score for MIPS eligible clinicians, including APM Entity groups reporting through the CMS Web Interface. Those policies and proposed changes in section II.C.7.a.(1)(h)(ii) of this proposed rule would apply in the same manner under the APM scoring standard except as otherwise noted in this section of the proposed rule. However, we propose not to subject MIPS APM Web Interface reporters to a 3 point floor because we do not believe it is necessary to apply this transition year policy to eligible clinicians participating in previously established MIPS APMs.

(C) Incentives to Report High Priority Measures

In the CY 2017 Quality Payment Program final rule, we finalized that for CMS Web Interface reporters, we will apply bonus points based on the finalized set of measures reportable through the CMS Web Interface. (81 FR 77291 through 77294). We will assign two bonus points for reporting two or more outcome or patient experience measures and one bonus point for reporting any other high priority measure, beyond the first high priority measure. We note that in addition to the measures required by the APM to be submitted through the CMS Web Interface, APM Entities in the Shared Savings Program and Next Generation ACO Models must also report the CAHPS for ACOs survey and we propose that beginning for the 2020 payment year forward they may receive bonus points under the APM scoring standard for submitting that measure. Participants in MIPS APMs, like all MIPS eligible clinicians, are also subject to the 10 percent cap on bonus points for reporting high priority measures. APM Entities reporting through the CMS Web Interface will only receive bonus points if they submit a high priority measure with a performance rate that is greater than zero, provided that the measure meets the case minimum requirements.

(D) Scoring Quality Improvement

Beginning in the CY 2018 performance year, section 1848(q)(5)(D)(i)(I) of the Act requires us to score improvement for the MIPS quality performance category for MIPS eligible clinicians, including those participating in MIPS APMs, if data sufficient to measure quality improvement are available. We propose to calculate the quality improvement score using the methodology described in section II.C.7.a.(1)(i) for scoring quality improvement for eligible clinicians submitting quality measures via the CMS Web Interface. We believe aligning the scoring methodology used for all CMS Web Interface submissions will minimize confusion among MIPS eligible clinicians receiving a MIPS score, including those participating in MIPS APMs.

(E) Total Quality Performance Category Score for CMS Web Interface Reporters

We propose to calculate the total quality percent score for MIPS eligible clinicians using the CMS Web Interface according to the methodology described

in section II.C.7.a.(1)(h)(2) of this proposed rule.

We seek comment on our proposed quality performance category scoring methodology for CMS Web Interface reporters.

(ii) Other MIPS APMs

We propose to define the term Other MIPS APM at § 414.1305 as a MIPS APM that does not require reporting through the CMS Web Interface. We propose to add this definition as we believe it will be useful in discussing our policies for the APM scoring standard. In the 2018 MIPS performance period, Other MIPS APMs will include the Comprehensive ESRD Care Model, the Comprehensive Primary Care Plus Model (CPC+), and the Oncology Care Model.

(A) Quality Measures

In the CY 2017 Quality Payment Program final rule, we explained that current MIPS APMs have requirements regarding the number of quality measures, measure specifications, as well as the measure reporting method(s) and frequency of reporting, and have an established mechanism for submission of these measures to us within the structure of the specific MIPS APM. We explained that operational considerations and constraints interfered with our ability to use the quality measure data from some MIPS APMs for the purpose of satisfying MIPS data submission requirements for the quality performance category for the first performance year. We concluded that there was insufficient time to adequately implement changes to the current MIPS APM quality measure data collection timelines and infrastructure in the first performance year to conduct a smooth hand-off to the MIPS system that would enable use of APM quality measure data to satisfy the MIPS quality performance category requirements in the first MIPS performance year (81 FR 77264). Out of concern that subjecting MIPS eligible clinicians who participate in MIPS APMs to multiple, potentially duplicative or inconsistent performance assessments could undermine the validity of testing or performance evaluation under the MIPS APMs; and that there was insufficient time to make adjustments in operationally complex systems and processes related to the alignment, submission and collection of APM quality measures for purposes of MIPS, we used our authority under section 1115A(d)(1) to waive certain requirements of section 1848(q).

We finalized that for the first MIPS performance year only, for MIPS eligible clinicians participating in APM Entities in Other MIPS APMs, the weight for the quality performance category is zero (81 FR 77268). To avoid risking adverse operational or program evaluation consequences for MIPS APMs while we worked toward incorporating MIPS APM quality measures into scoring for future performance years, we used the authority provided by section 1115A(d)(1) of the Act to waive the quality performance category weight required under section 1848(q)(5)(E)(i)(I) of the Act, and we indicated that with the reduction of the quality performance category weight to zero, it was unnecessary to establish for MIPS APMs a final list of quality measures as required under section 1848(q)(2)(D) of the Act or to specify and use quality measures in determining the MIPS final score for these MIPS eligible clinicians. As such, we further waived the requirements under sections 1848(q)(2)(D), 1848(q)(2)(B)(i) and 1848(q)(2)(A)(i) of the Act to establish a final list of quality measures (using certain criteria and processes); and to specify and use, respectively, quality measures in calculating the MIPS final score for the first MIPS performance year.

In the CY 2017 Quality Payment Program final rule, we anticipated that beginning with the second MIPS performance year, the APM quality measure data submitted to us during the MIPS performance year would be used to derive a MIPS quality performance score for APM Entities in all MIPS APMs.

We also anticipated that it may be necessary to propose policies and waivers of requirements of the statute, such as section 1848(q)(2)(D) of the Act, to enable the use of non-MIPS quality measures in the quality performance category score. We anticipated that by the second performance year we would have had sufficient time to resolve operational constraints related to use of separate quality measure systems and to adjust quality measure data submission timelines. Accordingly, we stated our intention to, in future rulemaking, use our section 1115A(d)(1) waiver authority to establish that the quality measures and data that are used to evaluate performance for APM Entities in MIPS APMs would be used to calculate a MIPS quality performance score under the APM scoring standard.

We have since designed the means to overcome the operational constraints that prevented us from scoring quality under the APM scoring standard in the first performance year, and we propose to adopt quality measures for use under the APM scoring standard, and begin collecting MIPS APM quality measure performance data in order to generate a MIPS quality performance category score for APM Entities participating in MIPS APMs beginning with the 2018 performance year.

(aa) APM Measures for MIPS

In the CY 2017 Quality Payment Program final rule, we explained the concerns that led us to express our intent to use the quality measures and data that apply in the MIPS APM for purposes of the APM scoring standard, including concerns about the application of multiple, potentially duplicative or inconsistent performance assessments that could negatively impact our ability to evaluate MIPS APMs (81 FR 77246). Additionally, the quality and cost/utilization measures that are used to calculate performance-based payments in MIPS APMs may vary from one MIPS APM to another. Factors such as the type and quantity of measures required, the MIPS APM's particular measure specifications, how frequently the measures must be reported, and the mechanisms used to collect or submit the measures all add to the diversity in the quality and cost/utilization measures used to evaluate performance among MIPS APMs. Given these concerns and the differences between and among the quality measures used to evaluate performance within MIPS APMs as opposed to those used more generally under MIPS, we propose to use our authority under section 1115A(d)(1) of the Act to waive requirements under section 1848(q)(2)(D) of the Act, which requires the Secretary to use certain criteria and processes to establish an annual MIPS final list of quality measures from which all MIPS eligible clinicians may choose measures for purposes of assessment, and instead to establish a MIPS APM quality measure list for purposes of the APM scoring standard. The MIPS APM quality measure list would be adopted as the final list of MIPS quality measures under the APM scoring standard, and would reflect the quality measures that are used to evaluate performance on quality within each MIPS APM.

The MIPS APM quality measure list we propose in Table 13, would define distinct measure sets for participants in each MIPS APM for purposes of the APM scoring standard, based on the measures that are used by the APM, and for which data will be collected by the close of the MIPS submission period. The measure sets on the MIPS APM measure list would represent all possible measures which may contribute to an APM Entity's MIPS score for the MIPS quality performance

category, and may include measures that are the same as or similar to those used by MIPS. However, measures may ultimately not be used for scoring if a measure's data becomes inappropriate or unavailable for scoring; for example, if a measure's clinical guidelines are changed or the measure is otherwise modified by the APM during the performance year, the data collected during that performance year would not be uniform, and as such may be rendered unusable for purposes of the APM scoring standard (See Tables 14, 15, and 16).

(B) Measure Requirements for Other MIPS APMs

Because the quality measure sets for each Other MIPS APM are unique, we propose to calculate the MIPS quality performance category score using APM-specific quality measures. For purposes of the APM scoring standard, we will score only measures that: (1) Are tied to payment as described under the terms of the APM, (2) are available for scoring near the close of the MIPS submission period, (3) have a minimum of 20 cases available for reporting, and (4) have an available benchmark. We discuss each of these requirements for Other MIPS APM quality measures below.

(aa) Tied to Payment

For purposes of the APM scoring standard, we will consider a measure to be tied to payment if an APM Entity group will receive a payment adjustment or other incentive payment under the terms of the APM, based on the APM Entity's performance on the measure.

(bb) Available for Scoring

Some MIPS APM quality measure results are not available until late in the calendar year subsequent to the MIPS performance year, which would prevent us from including them in the MIPS APM quality performance category score due to the larger programmatic timelines for providing MIPS eligible clinician performance feedback by July and issuing budget-neutral MIPS payment adjustments. Consequently, we propose to only use the MIPS APM quality measure data that are submitted by the close of the MIPS submission period and are available for scoring in time for inclusion to calculate a MIPS quality performance category score. Measures are to be submitted according to requirements under the terms of the APM; the measure data will then be aggregated and prepared for submission to MIPS for the purpose of creating a MIPS quality performance category score.

We believe using the Other MIPS APMs' quality measure data that have been submitted no later than the close of the MIPS submission period and have been processed and made available to MIPS for scoring in time to calculate a MIPS quality performance category score is consistent with our intent to decrease duplicative reporting for MIPS eligible clinicians who would otherwise need to report quality measures to both MIPS and their APM. Going forward, these are the measures to which we are referring when we limit scoring to measures that are available near the close of the MIPS submission period.

(cc) 20 Case Minimum

We also believe that a 20 case minimum, in alignment with the one finalized generally under MIPS in the CY 2017 Quality Payment Program final rule (81 FR 77288), is necessary to ensure the reliability of the measure data submitted, as explained the CY 2017 Quality Payment Program final rule.

As under the general policy for MIPS, when an APM Entity reports a quality measure that includes less than 20 cases, that measure would receive a null score for that measure's achievement points, and the measure would be removed from both the numerator and the denominator of the MIPS quality performance category percentage. We propose to apply this policy under the APM scoring standard.

(dd) Available Benchmark

An APM Entity's score on each quality measure would be calculated in part by comparing the APM Entity's performance on the measure with a benchmark performance score. Therefore, we would need all scored measures to have a benchmark available by the time that the MIPS quality performance category score is calculated, in order to make that comparison.

We propose that, for the APM scoring standard, the benchmark score used for a quality measure would be the benchmark used in the MIPS APM for calculation of the performance based payments, where such a benchmark is available. If the APM does not produce a benchmark score for a reportable measure that is included on the APM measures list, we would use the benchmark score for the measure that is used for the MIPS quality performance category generally (outside of the APM scoring standard) for that performance year, provided the measure specifications for the measure are the same under both the MIPS final list and the APM measures list. If neither the APM nor MIPS has a benchmark available for a reported measure, the APM Entity that reported that measure would receive a null score for that measure's achievement points, and the measure would be removed from both the numerator and the denominator of the quality performance category percentage.

(C) Calculating the Quality Performance Category Percent Score

Eligible clinicians who participate in Other MIPS APMs are subject to specific quality measure reporting requirements within these APMs. To best align with APM design and objectives, we propose that the minimum number of required measures to be reported for the APM scoring standard would be the minimum number of quality measures that are required by the MIPS APM and are collected and available in time to be included in the calculation for the APM Entity score under the APM scoring standard. For example, if an Other MIPS APM requires participating APM Entities to report nine of 14 quality measures by a specific date and the APM Entity misses the MIPS submission deadline, then for the purposes of calculating an APM Entity quality performance category score, the APM Entity would receive a zero for those measures. An APM Entity that does not submit any APM quality measures by the MIPS submission deadline would receive a zero for its MIPS APM quality performance category percent score for the performance year.

We propose that if an APM Entity submits some, but not all of the measures required by the MIPS APM by the close of the MIPS submission period, the APM Entity would receive points for the measures that were submitted, but would receive a score of zero for each remaining measure between the number of measures reported and the number of measures required by the APM that were available for scoring.

For example, if an APM Entity in the above hypothetical MIPS APM submits quality performance data on three of the APM's measures, instead of the required nine, the APM Entity would receive quality points in the APM scoring standard quality performance category percent score for the three measures it submitted, but would receive zero points for each of the six remaining measures that were required under the terms of the MIPS APM. On the other hand, if an APM Entity reports on more than the minimum number of measures required to be reported under the MIPS APM and the measures meet the other

criteria for scoring, only the measures with the highest scores, up to the number of measures required to be reported under the MIPS APM, would be counted; however, any bonus points earned by reporting on measures beyond the minimum number of required measures would be awarded.

If a measure is reported but fails to meet the 20 case minimum or does not have a benchmark available, there would be a null score for that measure, and it would be removed from both the numerator and the denominator, so as not to negatively affect the APM Entity's quality performance category score.

We propose to assign bonus points for reporting high priority measures or measures with end-to-end CEHRT reporting as described for general MIPS scoring in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77299).

(aa) Quality Measure Benchmarks

An APM Entity's MIPS quality measure score will be calculated by comparing the APM Entity's performance on a given measure with a benchmark performance score. We propose that the benchmark score used for a quality measure would be the benchmark used by the MIPS APM for calculation of the performance based payments within the APM, if possible, in order to best align the measure performance outcomes between the APM and MIPS programs. If the MIPS APM does not produce a benchmark score for a reportable measure that will be available at the close of the MIPS submission period, the benchmark score for the measure that is used for the MIPS quality performance category generally for that performance year would be used, provided the measure specifications are the same for both. If neither the APM nor MIPS has a benchmark available for a reported measure, the APM Entity that reported that measure will receive a null score for that measure's achievement points, and the measure will be removed from both the numerator and the denominator of the quality performance category percentage.

We are proposing that for measures that are pay for reporting or which do not measure performance on a continuum of performance, we will consider these measures to be lacking a benchmark and they will be treated as such. For example, if a model only requires that an APM Entity must surpass a threshold and does not measure APM Entities on performance beyond surpassing a threshold, we would not consider such a measure to measure performance on a continuum.

We propose to score quality measure performance under the APM scoring standard using a percentile distribution, separated by decile categories, as described in the finalized MIPS quality scoring methodology (81 FR 77282 through 77284). For each benchmark, we will calculate the decile breaks for measure performance and assign points based on the benchmark decile range into which the APM Entity's measure performance falls.

We propose to use a graduated points-assignment approach, where a measure is assigned a continuum of points out to one decimal place, based on its place in the decile. For example, a raw score of 55 percent would fall within the sixth decile of 41.0 percent to 61.9 percent and would receive between 6.0 and 6.9 points.

We seek comment on this proposed method.

TABLE 11—BENCHMARK DECILE DISTRIBUTION

Sample benchmark decile	Sample quality measure (%)	Graduated points (with no floor)
Example Benchmark Decile 1	0–9.9	1.0–1.9
Example Benchmark Decile 2	10.0–17.9	2.0–2.9
Example Benchmark Decile 3	18.0–22.9	3.0–3.9
Example Benchmark Decile 4	23.0–35.9	4.0–4.9
Example Benchmark Decile 5	36.0–40.9	5.0–5.9
Example Benchmark Decile 6	41.0–61.9	6.0–6.9
Example Benchmark Decile 7	62.0–68.9	7.0–7.9
Example Benchmark Decile 8	69.0–78.9	8.0–8.9
Example Benchmark Decile 9	79.0–84.9	9.0–9.9
Example Benchmark Decile 10	85.0–100	10.0

(bb) Assigning Quality Measure Points Based on Achievement

For the APM scoring standard quality performance category, we propose that each APM Entity that reports on quality measures would receive between 1 and 10 achievement points for each measure reported that can be reliably scored against a benchmark, up to the number of measures that are required to be reported by the APM. Because measures that lack benchmarks or 20 reported cases are removed from the numerator and denominator of the quality performance category percentage, it is unnecessary to include a point-floor for scoring of Other MIPS APMs. Similarly, because the quality measures reported by the MIPS APM for MIPS eligible clinicians under the APM scoring standard are required to be submitted to the APM under the terms of participation in the APM, and the MIPS eligible clinicians do not select their APM measures, there will be no cap on topped out measures for MIPS APM participants being scored under the APM scoring standard, which differs from the policy for other MIPS eligible clinicians proposed at section II.C.7.a.(2)(c) of this proposed rule.

Beginning in the 2018 MIPS performance year, we propose that APM Entities in MIPS APMs, like other MIPS eligible clinicians, would be eligible to receive bonus points for the MIPS quality performance category for reporting on high priority measures or measures submitted via CEHRT (for example, end-to-end submission) according to the criteria described in section II.C.7.a.(1) of this proposed rule. For each Other MIPS APM, we propose to identify whether any of their available measures meets the criteria to receive a bonus, and add the bonus points to the quality achievement points. Further, we propose that the total number of awarded bonus points may not exceed 10 percent of the APM Entity's total available achievement points for the MIPS quality performance category score.

To generate the APM Entity's quality performance category percentage, achievement points would be added to any applicable bonus points, and then divided by the total number of available achievement points, with a cap of 100

percent. For more detail on the MIPS quality performance category percentage score calculation, we refer readers to section II.C.7.a.(1) of this proposed rule.

Under the APM scoring standard for Other MIPS APMs, the number of available achievement points would be the number of measures required under the terms of the APM and available for scoring multiplied by ten. If, however, an APM Entity reports on a required measure that fails the 20 case minimum requirement, or which has no available benchmark for that performance year, the measure would receive a null score and all points from that measure would be removed from both the numerator and the denominator.

For example, if an APM Entity reports on four out of four measures required to be reported by the MIPS APM, and receives an achievement score of five on each and no bonus points, the APM Entity's quality performance category percentage would be [(5 points × 4 measures) + 0 bonus points]/(4 measures × 10 max available points), or 50 percent. If, however, one of those measures failed the 20 case minimum requirement or had no benchmark available, that measure would have a null value and would be removed from both the numerator and denominator to create a quality performance category percentage of [(5 points × 3 measures) + 0 bonus points]/(3measures × 10 max available points), or 50 percent.

If an APM Entity fails to meet the 20 case minimum on all available APM measures, that APM Entity would have its quality performance category score reweighted to zero, as described below.

We request comment on the above proposals for calculating the quality category percent score.

(D) Quality Improvement Scoring

Beginning in the 2018 performance year, we propose to score improvement as well as achievement in the quality performance category.

For the APM scoring standard, we propose that the quality improvement percentage points would be awarded based on the following formula:

Quality Improvement Score = (Absolute Improvement/Previous Year Quality Performance Category Percent Score Prior to Bonus Points)/10

For a more detailed discussion of improvement scoring for the quality performance category under the APM scoring standard, we refer readers to the discussion on calculating improvement at the quality performance category level for MIPS at section II.C.7.a.(1)(i) of this proposed rule.

(E) Calculating Total Quality Performance Category Score

We propose that the APM Entity's total quality performance category score would be equal to [(achievement points + bonus points)/total available achievement points] + quality improvement score. The APM Entity's total quality performance category score may not exceed 100 percent. We request comment on the above proposed quality scoring methodology.

We seek comment on the proposed quality performance category scoring methodology for APM Entities participating in Other MIPS APMs.

(c) Improvement Activities Performance Category

As finalized in the CY 2017 Quality Payment Program final rule, for all MIPS APMs we will assign the same improvement activities score to each APM Entity based on the activities involved in participation in a MIPS APM. APM Entities will receive a minimum of one half of the total possible points. This policy is in accordance with section 1848(q)(5)(C)(ii) of the Act. In the event that the assigned score does not represent the maximum improvement activities score, the APM Entity group will have the opportunity to report additional improvement activities to add points to the APM Entity level score.

(d) Advancing Care Information Performance Category

In the CY 2017 Quality Payment Program final rule, we finalized our policy to attribute one score to each MIPS eligible clinician in an APM Entity group by looking for both individual and group TIN level data submitted for a MIPS eligible clinician, and using the highest available score (81 FR 77268). We will then use these scores to create an APM Entity's score based on the average of the highest scores available for all MIPS eligible clinicians in the APM Entity group. If an individual or TIN did not report on the advancing care information performance category, they will contribute a zero to the APM Entity's aggregate score. Each MIPS eligible clinician in an APM Entity group will receive one score, weighted equally with the scores of every other MIPS eligible clinician in the APM Entity group, and we will use these to calculate a single APM Entity-level advancing care information performance category score.

We refer readers to section II.C.6.f.(6) of this proposed rule for our summary of proposed changes related to scoring the advancing care information performance category.

(i) Special Circumstances

As described in the CY 2017 Quality Payment Program final rule (81 FR 77238–77245), under the generally applicable MIPS scoring standard, we will assign a weight of zero percent to the advancing care information performance category in the final score for MIPS eligible clinicians who meet specific criteria: hospital-based MIPS eligible clinicians, MIPS eligible clinicians who are facing a significant hardship, and certain types of non-physician practitioners (NPs, PAs, CRNAs, CNSs) who are MIPS eligible clinicians. In section II.C.7.a.(6) of this proposed rule, we are also proposing to include in this weighting policy ASC-based MIPS eligible clinicians and MIPS eligible clinicians who are using decertified EHR technology.

Under the APM scoring standard, we propose that if a MIPS eligible clinician who qualifies for a zero percent weighting of the advancing care information performance category in the final score is part of a TIN that includes one or more MIPS eligible clinicians who do not qualify for a zero percent weighting, we would not apply the zero percent weighting to the qualifying MIPS eligible clinician, and the TIN would still be required to report on behalf of the group, although the TIN would not need to report data for the qualifying MIPS eligible clinician. All MIPS eligible clinicians in the TIN would count towards the TIN's weight when calculating an aggregated APM Entity score for the advancing care information performance category.

If, however, the MIPS eligible clinician is a solo practitioner and qualifies for a zero percent weighting, or if all MIPS eligible clinicians in a TIN qualify for the zero percent weighting, the TIN would not be required to report on the advancing care information performance category, and if the TIN chooses not to report that TIN would be assigned a weight of 0 when calculating the APM Entity's advancing care information performance category score.

If advancing care information data are reported by one or more TINs in an APM Entity, an advancing care information performance category score will be calculated for, and will be applicable to, all MIPS eligible clinicians in the APM Entity group. If all MIPS eligible clinicians in all TINs in an APM Entity group qualify for a zero percent weighting of have the advancing care information performance category, or in the case of a solo practitioner who comprises an entire

APM Entity and qualifies for zero percent weighting, the advancing care information performance category would be weighted at zero percent of the final score, and the advancing care information performance category's weight would be redistributed to the quality performance category.

(4) Calculating Total APM Entity Score

(a) Performance Category Weighting

As discussed in section II.C.6.g.(3)(a) of this proposed rule, we propose to continue to use our authority to waive sections 1848(q)(2)(B)(ii) and 1848(q)(2)(A)(ii) of the Act to specify and use, respectively, cost measures; and to maintain the cost performance category weight of zero under the APM scoring standard for the 2018 performance period and subsequent MIPS performance periods. Because the cost performance category would be reweighted to zero that weight would need to be redistributed to other performance categories. We propose to use our authority under section 1115A(d)(1) to waive requirements under sections 1848(q)(5)(E)(i)(I)(bb), 1848(q)(5)(E)(i)(III) and 1848(q)(5)(E)(i)(IV) of the Act that prescribe the weights, respectively, for the quality, improvement activities, and ACI performance categories. We propose to weight the quality performance category score to 50 percent, the improvement activities performance category to 20 percent, and the advancing care information performance category to 30 percent of the final score for all APM Entities in Other MIPS APMs. We propose these weights to align the Other MIPS APM performance category weights with those assigned to the Web Interface reporters, which we adopted as explained in the CY 2017 Quality Payment Program final rule at 81 FR 77262 through 77263. We believe it is appropriate to align the performance category weights for APM Entities in MIPS APMs that require reporting through the Web Interface with those in Other MIPS APMs. By aligning the performance category weights among all MIPS APMs, we would create greater scoring parity among the MIPS eligible clinicians in MIPS APMs who are being scored under the APM scoring standard. These proposals are summarized in Table 12.

TABLE 12—APM SCORING STANDARD PERFORMANCE CATEGORY WEIGHTS—BEGINNING FOR THE 2018 PERFORMANCE PERIOD

MIPS performance category	APM entity submission requirement	Performance category score	Performance category weight (%)
Quality	The APM Entity will be required to submit quality measures to CMS as required by the MIPS APM. Measures available at the close of the MIPS submission period will be used to calculate the MIPS quality performance category score. If the APM Entity does not submit any APM required measures by the MIPS submission deadline, the APM Entity will be assigned a zero.	CMS will assign the same quality category performance score to each TIN/NPI in an APM Entity group based on the APM Entity's total quality score, derived from available APM quality measures.	50
Cost	The APM Entity group will not be assessed on cost under MIPS.	N/A	0
Improvement Activities	MIPS eligible clinicians do not need to report improvement activities data; if the CMS-assigned improvement activities score is below the maximum improvement activities score APM Entities will have the opportunity to submit additional improvement activities to raise the APM Entity improvement activity score.	CMS will assign the same improvement activities score to each APM Entity based on the activities involved in participation in the MIPS APM. APM Entities will receive a minimum of one half of the total possible points. In the event that the assigned score does not represent the maximum improvement activities score, the APM Entity will have the opportunity to report additional improvement activities to add points to the APM Entity level score.	20
Advancing Care Information.	Each MIPS eligible clinician in the APM Entity group is required to report advancing care information to MIPS through either group TIN or individual reporting.	We will attribute the same score to each MIPS eligible clinician in the APM Entity group. This score will be the highest score attributable to the TIN/NPI combination of each MIPS eligible clinician, which may be derived from either group or individual reporting. The scores attributed to each MIPS eligible clinicians will be averaged for a single APM Entity score.	30

It is possible that there could be instances where an Other MIPS APM has no measures available to score for the quality performance category for a MIPS performance period; for example, it is possible that none of the Other MIPS APM's measures would be available for calculating a quality performance category score by or shortly after the close of the MIPS submission period because the measures were removed due to changes in clinical practice guidelines. In addition, as explained in section II.C.6.g.(3)(d)(i) of this proposed rule, the MIPS eligible clinicians in an APM Entity may qualify for a zero percent weighting for the advancing care information performance category. In such instances, under the APM scoring standard, we propose to reweight the affected performance category to zero, in accordance with section 1848(q)(5)(F) of the Act.

If the quality performance category is reweighted to zero, we propose to reweight the improvement activities and advancing care information performance categories to 25 and 75 percent, respectively. If the advancing care information performance category is reweighted to zero, the quality performance category weight would be

increased to 80 percent. These proposals are summarized in Table 13.

TABLE 13—APM SCORING STANDARD PERFORMANCE CATEGORY WEIGHTS FOR OTHER MIPS APMS WITH PERFORMANCE CATEGORIES WEIGHTED TO 0—BEGINNING FOR THE 2018 PERFORMANCE PERIOD

MIPS performance category	APM entity submission requirement	Performance category score	Performance category weight (no quality) (%)	Performance category weight (no advancing care information) (%)
Quality	The APM Entity would not be assessed on quality under MIPS if no quality data are available at the close of the MIPS submission period. The APM Entity will submit quality measures to CMS as required by the MIPS APM.	CMS will assign the same quality category performance score to each TIN/NPI in an APM Entity group based on the APM Entity's total quality score, derived from available APM quality measures.	0	80
Cost	The APM Entity group will not be assessed on cost under MIPS.	N/A	0	0
Improvement Activities.	MIPS eligible clinicians do not need to report improvement activities data unless the CMS-assigned improvement activities scores is below the maximum improvement activities score.	CMS will assign the same improvement activities score to each APM Entity group based on the activities involved in participation in the MIPS APM. APM Entities will receive a minimum of one half of the total possible points. In the event that the assigned score does not represent the maximum improvement activities score, the APM Entity will have the opportunity to report additional improvement activities to add points to the APM Entity level score.	25	20
Advancing Care Information.	Each MIPS eligible clinician in the APM Entity group reports advancing care information to MIPS through either group TIN or individual reporting.	We will attribute the same score to each MIPS eligible clinician in the APM Entity group. This score will be the highest score attributable to the TIN/NPI combination of each MIPS eligible clinician, which may be derived from either group or individual reporting. The scores attributed to each MIPS eligible clinicians will be averaged for a single APM Entity score.	75	0

We seek comment on the proposed reweighting for APM Entities participating in MIPS APMs.

(b) Risk Factor Score

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, that section provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under the MIPS.

We refer readers to II.C.7.b.(1) of this proposed rule for a description of the risk factor adjustment and its application to APM Entities.

(c) Small Practice Bonus

We believe an adjustment for eligible clinicians in small practices (referred to herein as the small practice bonus) is appropriate to recognize barriers faced by small practices, such as unique challenges related to financial and other resources, environmental factors, and access to health information technology, and to incentivize eligible clinicians in small practices to participate in the Quality Payment Program and to overcome any performance discrepancy due to practice size.

We refer readers to section II.C.7.b.(2) of this proposed rule for a discussion of the small practice adjustment and its application to APM Entities.

(d) Final Score Methodology

In the CY 2017 Quality Payment Program final rule, we finalized the methodology for calculating a final score of 0–100 based on the four performance categories (81 FR 77320). We refer readers to section II.C.7.c. of this proposed rule for a discussion of the changes we are proposing for the final score methodology.

(5) MIPS APM Performance Feedback

In the CY 2017 Quality Payment Program final rule (81 FR 77270), we finalized that all MIPS eligible clinicians scored under the APM scoring standard will receive performance feedback as specified under section 1848(q)(12) of the Act on the quality and cost performance categories to the extent applicable, based on data collected in the September 2016 QRUR, unless they did not have data included in the September 2016 QRUR. Those eligible clinicians without data included in the September 2016 QRUR will not receive any performance feedback until performance data is available for feedback.

Beginning with the 2018 performance year, we propose that MIPS eligible clinicians whose MIPS payment adjustment is based on their score under the APM scoring standard will receive performance feedback as specified

under section 1848(q)(12) of the Act for the quality, advancing care information, and improvement activities performance categories to the extent data are available for the MIPS performance year. Further, we propose that in cases where performance data are not available for a MIPS APM performance category because the MIPS APM performance category has been weighted to zero for that performance year, we would not provide performance feedback on that MIPS performance category.

We believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population, the incentives of the APM must take priority over those offered by MIPS in order to ensure that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. The potential for different, conflicting messages in performance feedback provided by the APMs and that provided by MIPS may create uncertainty for MIPS eligible clinicians who are attempting to strategically transform their respective practices and succeed under the terms of the APM. Accordingly, under section 1115A(d)(1) and section 1899(f), for all performance years we propose to waive—for MIPS eligible clinicians participating in MIPS APMs—the requirement under section 1848(q)(12)(A)(i)(I) of the Act to provide performance feedback for the cost performance category.

We request comment on these proposals to waive requirements for performance feedback on the cost performance category indefinitely, and for the other performance categories in years for which the weight for those categories has been reweighted to zero.

(6) Summary of Proposals

In summary, we have proposed the following in this section:

- We propose to amend the regulation at § 414.1370(e) to identify the four assessment dates that would be used to identify the APM Entity group for purposes of the APM scoring standard, and to specify that the December 31 date will be used only to identify eligible clinicians on the APM Entity's Participation List for a MIPS APM that is a full TIN APM in order to add them to the APM Entity group that is scored under the APM scoring standard. We propose to use this fourth assessment date of December 31 to extend the APM scoring standard to only those MIPS eligible clinicians participating in MIPS APMs that are full TIN APMs, ensuring that an eligible clinician who joins the full TIN APM late in the performance year would be scored under the APM scoring standard.
- We propose to continue to weight the cost performance category under the APM scoring standard for Web Interface reporters at zero percent for the 2020 payment year forward.
- Aligned with our proposal to weight the cost performance category at zero percent, we propose not to take improvement into account for performance scores in the cost performance category for Web Interface reporters beginning with the 2020 MIPS Payment Year.
- We propose to score the CAHPS for ACOs survey, in addition to the CMS Web Interface measures that are used to calculate the MIPS APM quality performance category score for Web Interface reporters including the Shared Savings Program and Next Generation ACO Model), beginning in the 2018 performance year.
- We propose that, beginning for the 2018 performance year, eligible clinicians in MIPS APMs that are Web Interface reporters may receive bonus points under the APM scoring standard for submitting the CAHPS for ACOs survey.
- We propose to calculate the quality improvement score for MIPS eligible clinicians submitting quality measures via the CMS Web Interface using the methodology described in section II.C.7.a.(1)(i).
- We propose to calculate the total quality percent score for MIPS eligible clinicians using the CMS Web Interface according to the methodology described in section II.C.7.a.(1)(h)(2) of this proposed rule.
- We propose to establish a separate MIPS final list of quality measures for each Other MIPS APM that would be the quality measure list used for purposes of the APM scoring standard.
- We propose to calculate the MIPS quality performance category score for Other MIPS APMs using MIPS APM-specific quality measures. For purposes of the APM scoring standard, we would score only measures that: (1) Are tied to payment as described under the terms of the APM, (2) are available for scoring near the close of the MIPS submission period, (3) have a minimum of 20 cases available for reporting, and (4) have an available benchmark.
- We propose to only use the MIPS APM quality measure data that are submitted by the close of the MIPS submission period and are available for scoring in time for inclusion to calculate a MIPS quality performance category score.
- We propose that, for the APM scoring standard, the benchmark score used for a quality measure would be the benchmark used in the MIPS APM for calculation of the performance based payments, where such a benchmark is available. If the APM does not produce a benchmark score for a reportable measure that is included on the APM measures list, we would use the benchmark score for the measure that is used for the MIPS quality performance category generally (outside of the APM scoring standard) for that performance year, provided the measure specifications for the measure are the same under both the MIPS final list and the APM measures list.
- We propose that the minimum number of quality measures required to be reported for the APM scoring standard would be the minimum number of quality measures that are required within the MIPS APM and are collected and available in time to be included in the calculation for the APM Entity score under the APM scoring standard. We propose that if an APM Entity submits some, but not all of the measures required by the MIPS APM by the close of the MIPS submission period, the APM Entity would receive points for the measures that were submitted, but would receive a score of zero for each remaining measure between the number of measures reported and the number of measures required by the APM that were available for scoring.
- We propose that the benchmark score used for a quality measure would be the benchmark used by the MIPS APM for calculation of the performance based payments within the APM, if possible, in order to best align the measure performance outcomes between the two programs. We are proposing that for measures that are pay for reporting or which do not measure performance on a continuum of performance, we will consider these measures to be lacking a benchmark and they will be treated as such.
- We propose to score quality measure performance under the APM scoring standard using a percentile distribution, separated by decile categories, as described in the finalized MIPS quality scoring methodology. We propose to use a graduated points-assignment approach, where a measure is assigned a continuum of points out to one decimal place, based on its place in the decile.
- We propose that each APM Entity that reports on quality measures would receive between 1 and 10 achievement points for each measure reported that can be reliably scored against a benchmark, up to the number of

measures that are required to be reported by the APM.

• We propose that APM Entities in MIPS APMs, like other MIPS eligible clinicians, would be eligible to receive bonus points for the MIPS quality performance category for reporting on high priority measures or measures submitted via CEHRT. For each Other MIPS APM, we propose to identify whether any of their available measures meets the criteria to receive a bonus, and add the bonus points to the quality achievement points.

• Beginning in the 2018 performance year, we propose to score improvement as well as achievement in the quality performance category. For the APM scoring standard, we propose that the improvement percentage points would be awarded based on the following formula:

Quality Improvement Score = (Absolute Improvement/Previous Year Quality Performance Category Percent Score Prior to Bonus Points)/10.

• We propose that the APM Entity's total quality performance category score would be equal to [(achievement points + bonus points)/total available achievement points] + quality improvement score.

• Under the APM scoring standard, we propose that if a MIPS eligible clinician who qualifies for a zero percent weighting of the advancing care information performance category in the final score is part of a TIN that includes one or more MIPS eligible clinicians who do not qualify for a zero percent weighting, we would not apply the zero percent weighting to the qualifying MIPS eligible clinician, and the TIN would still be required to report on behalf of the group, although the TIN would not need to report data for the qualifying MIPS eligible clinician.

• We propose to maintain the cost performance category weight of zero for Other MIPS APMs under the APM scoring standard for the 2020 MIPS payment year and subsequent MIPS payment years. Because the cost performance category would be reweighted to zero that weight would need to be redistributed to other performance categories. We propose to align the Other MIPS APM performance category weights with those proposed for Web Interface reporters and weight the quality performance category to 50 percent, the improvement activities performance category to 20 percent, and the advancing care information performance category to 30 percent of the APM Entity final score.

• It is possible that none of the Other MIPS APM's measures would be available for calculating a quality performance category score by or shortly after the close of the MIPS submission period, for example, due to changes in clinical practice guidelines. In addition, the MIPS eligible clinicians in an APM Entity may qualify for a zero percent weighting for the advancing care information performance category. In such instances, under the APM scoring standard, we propose to reweight the affected performance category to zero.

• Beginning with the 2018 performance year, we propose that MIPS eligible clinicians whose MIPS payment adjustment is based on their score under the APM scoring standard will receive performance feedback as specified under section 1848(q)(12) of the Act for the quality, advancing care information, and improvement activities performance categories to the extent data are available for the MIPS performance year. Further, we propose that in cases where the MIPS APM performance category has been weighted to zero for that performance year, we would not provide performance feedback on that MIPS performance category.

The following tables represent the measures being introduced for notice and comment, and would serve as the measure set used by participants in the identified MIPS APMs in order to create a MIPS score under the APM scoring standard, as described in section II.C.6.g.(3)(b)(ii)(A) of this proposed rule. Once this list is finalized, no measures may be added to this list.

TABLE 14—MIPS APM MEASURES LIST—ONCOLOGY CARE MODEL

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode.	NA	Effective Clinical Care	Percentage of OCM-attributed FFS beneficiaries who were had an acute-care hospital stay during the measurement period.	NA
Risk-adjusted proportion of patients with all-cause ED visits or observation stays that did not result in a hospital admission within the 6-month episode.	NA	Effective Clinical Care	Percentage of OCM-attributed FFS beneficiaries who had an ER visit that did not result in a hospital stay during the measurement period.	
Proportion of patients who died who were admitted to hospice for 3 days or more.	NA	Effective Clinical Care	Percentage of OCM-attributed FFS beneficiaries who died and spent at least 3 days in hospice during the measurement time period.	NA
Oncology: Medical and Radiation—Pain Intensity Quantified.	0384/143	Person and Caregiver Centered Experience.	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundations (PCPI).
Oncology: Medical and Radiation—Plan of Care for Pain.	0383/144	Person and Caregiver Centered Experience.	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology.
Preventive Care and Screening: Screening for Depression and Follow-Up Plan.	0418/134	Community/Population Health.	Percentage of patients aged 12 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services.

TABLE 14—MIPS APM MEASURES LIST—ONCOLOGY CARE MODEL—Continued

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
Patient-Reported Experience of Care.	NA	Person and Caregiver Centered Experience.	Summary/Survey Measures may include: —Overall measure of patient experience ..... —Exchanging Information with Patients ..... —Access ..... —Shared Decision Making ..... —Enabling Self-Management ..... —Affective Communication	NA
Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer.	0390/104	Effective Clinical Care	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam and radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin releasing hormone] agonist or antagonist).	American Urological Association Education and Research.
Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer.	0223	Communication and Care Coordination.	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons.
Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB—III hormone receptor negative breast cancer.	0559	Communication and Care Coordination.	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB—III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons.
Trastuzumab administered to patients with AJCC stage I (T1c)—III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy.	1858/450	Efficiency and Cost Reduction.	Proportion of female patients (aged 18 years and older) with AJCC stage I (Tlc)—III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy.	American Society of Clinical Oncology.
Breast Cancer: Hormonal Therapy for Stage I (T1b)—IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.	0387	Communication and Care Coordination.	Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA-convened Physician Consortium for Performance Improvement.
Documentation of Current Medications in the Medical Record.	0419/130	Patient Safety	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the counters, herbals, and vitamin/mineral/dietary AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services.

TABLE 15—MIPS APM MEASURES LIST—COMPREHENSIVE ESRD CARE

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
ESCO Standardized Mortality Ratio.	0101/154	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within for Quality 12 months.	National Committee for Quality Assurance.
Falls: Screening, Risk Assessment and Plan of Care to Prevent Future Falls.	0101/154	Communication and Coordination.	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within for Quality 12 months.	National Committee for Quality Assurance.
Advance Care Plan	0326/47	Patient Safety	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance.

TABLE 15—MIPS APM MEASURES LIST—COMPREHENSIVE ESRD CARE—Continued

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
ICH-CAHPS: Nephrologists' Communication and Caring.	0258	Person and Caregiver Centered Experience and Outcome.	Summary/Survey Measures may include: —Getting timely care, appointments, and information. —How well providers communicate ..... —Patients' rating of provider ..... —Access to specialists ..... —Health promotion and education ..... —Shared decision-making ..... —Health status and functional status ..... —Courteous and helpful office staff ..... —Care coordination ..... —Between visit communication ..... —Helping you to take medications as directed, and —Stewardship of patient resources	Agency for Healthcare Research and Quality.
ICH-CAHPS: ICH-CAHPS: Rating of Dialysis Center.	0258	Person and Caregiver Centered Experience and Outcome.	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	Agency for Healthcare Research and Quality.
ICH-CAHPS: Quality of Dialysis Center Care and Operations.	0258	.....	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	Agency for Healthcare Research and Quality.
ICH-CAHPS: Providing Information to Patients.	0258	.....	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	Agency for Healthcare Research and Quality.
ICH-CAHPS: Rating of Kidney Doctors.	0258	.....	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	Agency for Healthcare Research and Quality.
ICH-CAHPS: Rating of Dialysis Center Staff. ICH-CAHPS: Rating of Dialysis Center.	0258	.....	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	Agency for Healthcare Research and Quality.
Medication Reconciliation Post Discharge.	0554	Communication and Care Coordination.	The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following the discharge in the office by the physicians, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18–64 years of age. • Reporting Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and Older.	National Committee for Quality Assurance.
Diabetes Care: Eye Exam ...	0055/117	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance.
Diabetes Care: Foot Exam ..	0056/163	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.	National Committee for Quality Assurance.
Influenza Immunization for the ESRD Population.	0041/110, 0226.	Community/Population Health.	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Kidney Care Quality Alliance (KCQA).
Pneumococcal Vaccination Status.	0043/111	Community/Population Health.	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance.

TABLE 15—MIPS APM MEASURES LIST—COMPREHENSIVE ESRD CARE—Continued

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
Screening for Clinical Depression and Follow-Up Plan.	0418/134	Community/Population Health.	Percentage of patients aged 12 and older screened for depression on the date of the encounter and using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare and Medicaid Services.
Tobacco Use: Screening and Cessation Intervention.	0028/226	Community/Population Health.	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundations (PCPI).

TABLE 16—MIPS APM MEASURES LIST—COMPREHENSIVE PRIMARY CARE PLUS (CPC+)

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
Depression Remission at Twelve Months.	0710/370	Effective Clinical Care	Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ–9) score greater than nine who demonstrate remission at twelve months (+/− 30 days after an index visit) defined as a PHQ–9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ–9 score indicates a need for treatment.	Minnesota Community Measurement
Controlling High Blood Pressure.	0018/236	Effective Clinical Care	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
Diabetes: Eye Exam	0055/117	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%).	0059/001	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	National Committee for Quality Assurance
Use of High-Risk Medications in the Elderly.	0022/238	Patient Safety	Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	National Committee for Quality Assurance
Dementia: Cognitive Assessment.	NA/281	Effective Clinical Care	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI)
Falls: Screening for Future Fall Risk.	0101/318	Patient Safety	Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period.	National Committee for Quality Assurance
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.	0004/305	Effective Clinical Care	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
Closing the Referral Loop: Receipt of Specialist Report.	NA/374	Communication and Care Coordination.	Percentage of Patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare and Medicaid Services
Cervical Cancer Screening	0032/309	Effective Clinical Care	Percentage of women 21–64 years of age, who were screened for cervical cancer using either of the following criteria. • Women age 21–64 who had cervical cytology performed every 3 years. • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
Colorectal Cancer Screening.	0034/113	Effective Clinical Care	Percentage of patients, 50–75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	0028/226	Community/Population Health.	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundations (PCPI)

TABLE 16—MIPS APM MEASURES LIST—COMPREHENSIVE PRIMARY CARE PLUS (CPC+)—Continued

Measure name	NQF/Quality number (if applicable)	National quality strategy domain	Measure description	Primary measure steward
Breast Cancer Screening	2372/112	Effective Clinical Care	Percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
Preventive Care and Screening: Influenza Immunization.	0041/110	Community/Population Health.	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	PCPI(R) Foundation (PCPI[R])
Pneumonia Vaccination Status for Older Adults.	0043/111	Community/Population Health.	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
Diabetes: Medical Attention for Nephropathy.	0062/119	Effective Clinical Care	The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
Ischemic Vascular Disease (IVD): Use of Aspirin or Another.	0068/204	Effective Clinical Care	Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee Quality Assurance
Hypertension: Improvement in Blood Pressure.	NA/373	Effective Clinical Care	Percentage of patients aged 18–85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services (CMS)
Preventive Care and Screening: Screening for Depression and Follow-Up Plan.	0418/134	Community/Population Health.	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services (CMS)
Diabetes: Foot Exam	0056/163	Effective Clinical Care	The percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	NA/438	*Not provided in the measure*	Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: * Adults aged ≥21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR * Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR * Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70–189 mg/dL.	Quality Insights
Inpatient Hospital Utilization (IHU).	NA	.....	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance
Emergency Department Utilization (EDU).	NA	.....	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance
Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan.	0421	Community/Population Health.	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥18.5 and <25 kg/m2.	Centers for Medicare & Medicaid Services (CMS)
CAHPS	CPC+ specific; different than CAHPS for MIPS.	.....	CG-CAHPS Survey 3.0	AHRQ

7. MIPS Final Score Methodology

For the 2020 MIPS payment year, we intend to build on the scoring methodology we finalized for the transition year, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians, while continuing to prepare MIPS eligible clinicians for the performance threshold required for the 2021 MIPS payment year. Our rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and numerous moving parts.

As we continue to move forward in implementing the MIPS program, we strive to balance the statutory requirements and programmatic goals

with the ease of use, stability, and meaningfulness for MIPS eligible clinicians, while also emphasizing simplicity and scoring that is understandable for MIPS eligible clinicians. In this section, we propose refinements to the performance standards, the methodology for determining a score for each of the four performance categories (the ''performance category score''), and the methodology for determining a final score based on the performance category scores.

We intend to continue the transition of MIPS by proposing the following policies:

- Continuation of many transition year scoring policies in the quality performance category, with an adjustment to the number of achievement points available for measures that fail to meet the data completeness criteria, to encourage MIPS eligible clinician to meet data completeness while providing an exception for small practices;
- An improvement scoring methodology that rewards MIPS eligible clinicians who improve their performance in the quality and cost performance categories;
- A new scoring option for the quality and cost performance categories that allows facility-based MIPS eligible clinicians to be scored based on their facility's performance;
- Special considerations for MIPS eligible clinicians in small practices or those who care for complex patients; and
- Policies that allow multiple pathways for MIPS eligible clinicians to receive a neutral to positive MIPS payment adjustment.

We believe these sets of proposed policies will help clinicians smoothly transition from the transition year to the 2021 MIPS payment year, for which the performance threshold (which represents the final score that would earn a neutral MIPS adjustment) will be either the mean or median (as selected by the Secretary) of the MIPS final scores for all MIPS eligible clinicians from a previous period specified by the Secretary.

Unless otherwise noted, for purposes of this section II.C.7. on scoring, the term ''MIPS eligible clinician'' will refer to MIPS eligible clinicians that submit data and are scored at either the individual- or group-level, including virtual groups, but will not refer to MIPS eligible clinicians who elect facility-based scoring. The scoring rules for facility-based measurement are discussed in section II.C.7.a.(4). of this proposed rule. We also note that the APM scoring standard applies to APM Entities in MIPS APMs, and those policies take precedence where applicable; however, where those policies do not apply, scoring for MIPS eligible clinicians as described in this section II.C.7. on scoring will apply. We refer readers to section II.C.6.g. of this proposed rule for additional information about the APM scoring standard.

a. Converting Measures and Activities Into Performance Category Scores

(1) Policies That Apply Across Multiple Performance Categories

The detailed policies and proposals for scoring the four performance categories are described in detail in section II.C.7.a. of this proposed rule. However, as the four performance categories collectively create a single MIPS final score, there are several policies that apply across categories, which we discuss in section II.C.7.a.(1) of this proposed rule.

(a) Performance Standards

In accordance with section 1848(q)(3) of the Act, in the CY 2017 Quality Payment Program final rule, we finalized performance standards for the four performance categories. We refer readers to the CY 2017 Quality Payment Program final rule for a description of the performance standards against which measures and activities in the four performance categories are scored (81 FR 77271 through 77272).

As discussed in section II.C.7.a.(1)(b)(i) of this proposed rule, we are proposing to add an improvement scoring standard to the quality and cost performance categories starting for the 2020 MIPS payment year.

(b) Policies Related to Scoring Improvement

(i) Background

In accordance with section 1848(q)(5)(D)(i) of the Act, beginning with the 2020 MIPS payment year, if data sufficient to measure improvement are available, the final score methodology shall take into account improvement of the MIPS eligible clinician in calculating the performance score for the quality and cost performance categories and may take into account improvement for the improvement activities and advancing care information performance categories. In addition, section 1848(q)(3)(B) of the Act provides that the Secretary, in establishing performance standards for measures and activities for the MIPS performance categories, shall consider: Historical performance standards; improvement; and the opportunity for continued improvement. Section 1848(q)(5)(D)(ii) of the Act also provides that achievement may be weighted higher than improvement.

In the CY 2017 Quality Payment Program final rule, we summarized public comments received on the proposed rule regarding potential ways to incorporate improvement into the scoring methodology moving forward, including approaches based on methodologies used in the Hospital VBP Program, the Shared Savings Program, and Medicare Advantage 5-star Ratings Program (81 FR 77306 through 77308). We did not finalize a policy at that time on this topic and indicated we would take comments into account in developing a proposal for future rulemaking.

When considering the applicability of these programs to MIPS, we looked at the approach that was used to measure improvement for each of the programs and how improvement was incorporated into the overall scoring system. An approach that focuses on measure-level comparison enables a more granular assessment of improvement because performance on a specific measure can be considered and compared from year to year. All options that we considered last year use a standard set of measures that do not provide for choice of measures to assess performance; therefore, they are better structured to compare changes in performance based on the same measure from year to year. The aforementioned programs do not use a category-level approach; however, we believe that a category-level approach would provide a broader perspective, particularly in the absence of a standard set of measures, because it would allow for a more flexible approach that enables MIPS eligible clinicians to select measures and data submission mechanisms that can change from year to year and be more appropriate to their practice in a given year.

We believe that both approaches are viable options for measuring improvement. Accordingly, we believe that an appropriate approach for measuring improvement for the quality performance category and the cost performance category should consider the unique characteristics of each performance category rather than necessarily applying a uniform approach across both performance categories. For the quality performance category, clinicians are offered a variety of different measures which can be submitted by different mechanisms, rather than a standard set of measures or a single data submission mechanism.

For the cost performance category, however, clinicians are scored on the same set of cost measures to the extent each measure is applicable and available to them; clinicians cannot choose which cost measures they will be scored on. In addition, all of the cost measures are derived from administrative claims data with no additional submission required by the clinician.

When considering the applicability of these programs to MIPS, we also considered how scoring improvement is incorporated into the overall scoring system, including when only achievement or improvement is incorporated into a final score or when improvement and achievement are both incorporated into a final score.

We considered whether we could adapt the Hospital VBP Program's general approach for assessing improvement to MIPS and note that many commenters, in response to the CY 2017 Quality Payment Program proposed rule, recommended this methodology for MIPS because it is familiar to the health care community. However, we decided that the Hospital VBP Program's improvement scoring methodology, which compares changes in performance based on the same measure from year to year, is not fully translatable to MIPS for the quality performance category and the cost performance category. The scoring methodology used to assess achievement in the Hospital VBP Program, as required by section 1886(o)(5)(B)(ii) of the Act, does not reward points for achievement in the same method as MIPS, because hospitals that fall below the achievement threshold (the median performance during the benchmark period) are not awarded achievement points. We refer readers to the Hospital Inpatient VBP Program Final Rule (76 FR 26516 through 26525) for additional discussion of the Hospital VBP Program's scoring methodology. In addition, the Hospital VBP Program requires the use of either the achievement score or the improvement points, but not both, for the Program's performance scoring calculation. Adopting the Hospital VBP Program method for MIPS would require significant changes to the scoring methodology used for the quality and cost performance categories. For the quality performance category, there are a wide variety of measures available in MIPS, and clinicians have flexibility in selecting measures and submission mechanisms, with the potential for clinicians to select different measures from year to year, which would affect our ability to capture performance changes at the measure level.

We continue to believe that flexibility for clinicians to select meaningful measures is appropriate for MIPS, especially for the quality performance category. The Hospital VBP Program methodology, which relies on consistent measures from year to year in order to track improvement, would limit our ability to measure improvement in MIPS.

We also considered adopting the Shared Savings Program's approach for assessing improvement, where participants can receive bonus points for improving on quality measures over time. The Shared Savings Program methodology could be adopted without an underlying change to the scoring of achievement in the quality and cost performance categories with an approach that considers both achievement and improvement in its overall scoring calculation and would align MIPS and the Shared Savings Program. However, we believe that the Shared Savings Program's improvement methodology would not be appropriate for the MIPS quality performance category because we are again concerned about the wide variety of quality measures available in MIPS and the flexibility clinicians have in selecting measures and submission mechanisms that could affect our ability to capture performance changes at the measure level. We seek to balance a system that allows for meaningful measurement to clinicians and accommodates the various practice types by allowing for a choice of measures and submission mechanisms that may differ from year to year for the quality performance category. However, as we discuss in section II.C.7.a.(3)(a) of this proposed rule, we do believe the Shared Savings Program measure level methodology could be translated for cost measures in the cost performance category.

Finally, we also considered adopting the Medicare Advantage Program's 5-Star Rating approach for assessing improvement, where Medicare Advantage contracts are rated on quality and performance measures. Under this approach, we would identify an overall ''improvement measure score'' by comparing the underlying numeric data for measures from the prior year with the data from measures for the performance period. To obtain an ''improvement measure score'' MIPS eligible clinicians would need to have data for both years in at least half of the required measures for the quality performance category (81 FR 77307). We are again concerned that the wide variety of measures available in MIPS and the flexibility clinicians have in selecting different measures and submission mechanisms from year to year could affect our ability to capture performance changes at the measure level, particularly for the quality performance category. Accordingly, we do not believe this is an appropriate approach for the quality performance category. Although this approach could be considered for the cost performance category, we believe that the Shared Savings Program is more analogous to MIPS and that the improvement methodology used in that program is one with which more stakeholders in MIPS would be familiar.

After taking all of this into consideration, we are proposing two different approaches for scoring improvement from year to year. As described in section II.C.7.a.(2)(i)(i) of this proposed rule, we are proposing to measure improvement at the performance category level for the quality performance category score. Because clinicians can elect the submission mechanisms and quality measures that are most meaningful to their practice, and these choices can change from year to year, we want a flexible methodology that allows for improvement scoring even when the quality measures change. This is particularly important as we encourage MIPS eligible clinicians to move away from topped out measures and toward more outcome measures. We do not want the flexibility that is offered to MIPS eligible clinicians in the quality performance category to limit clinicians' ability to move towards outcome measures, or limit our ability to measure improvement. Our proposal for taking improvement into account as part of the quality performance category score is addressed in detail in sections II.C.7.a.(2)(i) through II.C.7.a.(2)(j) of this proposed rule.

We believe that there is reason to adopt a different methodology for scoring improvement for the cost performance category from that used for the quality performance category. In contrast to the quality performance category, for the cost performance category, MIPS eligible clinicians do not have a choice in measures or submission mechanisms; rather, all MIPS eligible clinicians are assessed on all measures based on the availability and applicability of the measure to their practice, and all measures are derived from administrative claims data. Therefore, for the cost performance category, we propose in section II.C.7.a.(3)(a)(i) of this proposed rule to measure improvement at the measure

level. We also note, that while we are statutorily required to measure improvement for the cost performance category beginning with the second MIPS payment year if data sufficient to measure improvement is available, we are also proposing at II.C.6.d.(2) of this proposed rule to weight the cost performance category at zero percent for the 2018 MIPS performance period/2020 MIPS payment year. Therefore, the improvement score for the cost performance category would not affect the MIPS final score for the 2018 MIPS performance period/2020 MIPS payment year and would be for informational purposes only.

We are not proposing to score improvement in the improvement activities performance category or the advancing care information performance category at this time, though we may address improvement scoring for these performance categories in future rulemaking.

We propose to amend § 414.1380(a)(1)(i) to add that improvement scoring is available for performance in the quality performance category and for the cost performance category at § 414.1380(a)(1)(ii) beginning with the 2020 MIPS payment year.

We invite public comment on our proposals to score improvement for the quality and cost performance categories starting with the 2020 MIPS payment year.

(ii) Data Sufficiency Standard To Measure Improvement

Section 1848(q)(5)(D)(i) of the Act requires us to measure improvement for the quality and cost performance categories of MIPS if data sufficient to measure improvement are available, which we interpret to mean that we would measure improvement when we can identify data from a current performance period that can be compared to data from a prior performance period or data that compares performance from year to year. In section II.C.7.a.(2)(i)(ii) of this proposed rule, we propose for the quality performance category that we would measure improvement when data are available because there is a performance category score for the prior performance period. In section II.C.7.a.(3)(a)(i) of this proposed rule, we propose for the cost performance category that we would measure improvement when data are available which is when there is sufficient case volume to provide measurable data on measures in subsequent years with the same identifier. We refer readers to the noted sections for details on these proposals.

(c) Scoring Flexibility for ICD–10 Measure Specification Changes During the Performance Period

The quality and cost performance categories rely on measures that use detailed measure specifications that include ICD–10–CM/PCS (''ICD–10'') code sets. We annually issue new ICD–10 coding updates, which are effective from October 1, through September 30 (*https://www.cms.gov/Medicare/Coding/ICD10/ICD10OmbudsmanandICD10CoordinationCenterICC.html*). As part of this update, codes are added as well as removed from the ICD–10 code set.

To provide scoring flexibility for MIPS eligible clinicians and groups for measures impacted by ICD–10 coding changes in the final quarter of the Quality Payment Program performance period—which may render the measures no longer comparable to the historical benchmark—we propose at § 414.1380(b)(1)(xviii) and § 414.1320(c)(2) to provide that we will assess performance on measures considered significantly impacted by ICD–10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018 through September 30, 2018, for the 2018 MIPS performance period). We believe it would be appropriate to assess performance for significantly impacted measures based on the first 9 months of the performance period, rather than the full 12 months, because the indicated performance for the last quarter could be affected by the coding changes rather than actual differences in performance. Performance on measures that are not significantly impacted by changes to ICD–10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31).

Any measure that relies on an ICD–10 code which is added, modified, or removed, such as in the measure numerator, denominator, exclusions, or exceptions, could have an impact on the indicated performance on the measure, although the impact may not always be significant. We propose an annual review process to analyze the measures that have a code impact and assess the subset of measures significantly impacted by ICD–10 coding changes during the performance period. Depending on the data available, we anticipate that our determination as to whether a measure is significantly impacted by ICD–10 coding changes would include these factors: A more than 10 percent change in codes in the measure numerator, denominator, exclusions, and exceptions; guideline changes or new products or procedures reflected in ICD–10 code changes; and feedback on a measure received from measure developers and stewards. We considered an approach where we would consider any change in ICD–10 coding to impact performance on a measure and thus only rely on the first 9 months of the 12-month performance period for such measures. However, we believe such an approach would be too broad and truncate measurement for too many measures where performance may not be significantly affected. We believe that our proposed approach ensures the measures on which individual MIPS eligible clinicians and groups will have their performance assessed are accurate for the performance period and are consistent with the benchmark set for the performance period.

We propose to publish on the CMS Web site which measures are significantly impacted by ICD–10 coding changes and would require the 9-month assessment. We propose to publish this information by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period, which is January 1, 2019 for the 2018 performance period.

We request comment on the proposal to address ICD–10 measures specification changes during the performance period by relying on the first 9 months of the 12-month performance period. We also request comment on potential alternate approaches to address measures that are significantly impacted due to ICD–10 changes during the performance period, including the factors we might use to determine whether a measure is significantly impacted.

(2) Scoring the Quality Performance Category for Data Submission via Claims, Data Submissions via EHR, Third Party Data Submission Options, CMS Web Interface, and Administrative Claims

Many comments submitted in response to the CY 2017 Quality Payment Program final rule requested additional clarification on our finalized scoring methodology for the 2019 MIPS payment year. To provide further clarity to MIPS eligible clinicians about the transition year scoring policies, before describing our proposed scoring policies for the 2020 MIPS payment year, we provide a summary of the scoring policies finalized in the CY 2017 Quality Payment Program final rule along with examples of how they apply under several scenarios.

In the CY 2017 Quality Payment Program final rule (81 FR 77286 through

77287), we finalized that the quality performance category would be scored by assigning achievement points to each submitted measure, which we refer to in this section of the proposed rule as ''measure achievement points'' and we propose to amend various paragraphs in § 414.1380(b)(1) to use this term in place of ''achievement points''. MIPS eligible clinicians can also earn bonus points for certain measures (81 FR 77293 through 77294; 81 FR 77297 through 77299), which we refer to as ''measure bonus points'', and we propose to amend § 414.1380(b)(1)(xiii) (which we propose to redesignate as § 414.1380(b)(1)(xiv) in this proposed rule),[7] § 414.1380(b)(1)(xiv) (which we propose to redesignate as § 414.1380(b)(1)(xv) in this proposed rule), and § 414.1380(b)(1)(xv) (which we propose to redesignate as § 414.1380(b)(1)(xvii) in this proposed rule) to use this term in place of ''bonus points''. The measure achievement points assigned to each measure would be added with any measure bonus points and then divided by the total possible points (§ 414.1380(b)(1)(xv) (which we propose to redesignate as § 414.1380(b)(1)(xvii)). In this section of the proposed rule we refer to the total possible points as ''total available measure achievement points'', and we propose to amend § 414.1380(b)(1)(xv) to use this term in place of ''total possible points''. We also propose to amend these terms in § 414.1380(b)(1)(xiii)(D) (which we propose to redesignate as § 414.1380(b)(1)(xiv)(D) in this proposed rule), and § 414.1380(b)(1)(xiv) (which we propose to redesignate as § 414.1380(b)(1)(xv) in this proposed rule).

This resulting quality performance category score is a fraction from zero to 1, which can be formatted as a percent; therefore, for this section, we will present the quality performance category score as a percent and refer to it as ''quality performance category percent score.'' We also propose to amend § 414.1380(b)(1)(xv) (which we propose to redesignate as § 414.1380(b)(1)(xvii) in this proposed rule) to use this term in place of ''quality performance category score''. Thus, the formula for the quality performance category percent score that we will use in this section is as follows:

(total measure achievement points + total measure bonus points)/total available measure achievement points = quality performance category percent score.

In the CY 2017 Quality Payment Program final rule, we finalized that for the quality performance category, an individual MIPS eligible clinician or group that submits data on quality measures via EHR, QCDR, qualified registry, claims, or a CMS-approved survey vendor for the CAHPS for MIPS survey will be assigned measure achievement points for 6 measures (1 outcome or, if an outcome measure is not available, other high priority measure and the next 5 highest scoring measures) as available and applicable, and will receive applicable measure bonus points for all measures submitted that meet the bonus criteria (81 FR 77282 through 77301).

In addition, for groups of 16 or more clinicians who meet the case minimum of 200, we will also automatically score the administrative claims-based all-cause hospital readmission measure as a seventh measure (81 FR 77287). For individual MIPS eligible clinicians and groups for whom the readmission measure does not apply, the denominator is generally 60 (10 available measure achievement points multiplied by 6 available measures). For groups for whom the readmission measure applies, the denominator is generally 70 points.

If we determined that a MIPS eligible clinician has fewer than 6 measures available and applicable, we will score only the number of measures that are available and adjust the denominator accordingly to the total available measure achievement points (81 FR 77291). We refer readers to section II.C.7.a.(2)(e) of this proposed rule, for a description of the validation process to determine measure availability.

For the 2019 MIPS payment year, a MIPS eligible clinician that submits quality measure data via claims, EHR, or third party data submission options (that is, QCDR, qualified registry, EHR, or CMS-approved survey vendor for the CAHPS for MIPS survey), can earn between 3 and 10 measure achievement points for quality measures submitted for the performance period of greater than or equal to 90 continuous days during CY 2017. A MIPS eligible clinician can earn measure bonus points (subject to a cap) if they submit additional high priority measures with a performance rate that is greater than zero, and that meet the case minimum and data completeness requirements, or submit a measure using an end-to-end electronic pathway. An individual MIPS eligible clinician that has 6 or more quality measures available and applicable will have 60 total available measure achievement points. For example, as shown in Table 17, if an individual MIPS eligible clinician submits 7 measures, including one required outcome measure and 2 additional high priority measures, the MIPS eligible clinician will be assigned points based on achievement for the required outcome measure and the next 5 measures with the highest number of measure achievement points. In this example, the second high priority measure has the lowest number of measure achievement points and therefore is not included in the total measure achievement points calculated (81 FR 77300), but the MIPS eligible clinician will still receive a bonus point for submitting a high priority measure (81 FR 77291 through 77294). We note that in the CY 2017 Quality Payment Program proposed rule, we proposed that bonus points would be available for high priority measures that are not scored (not included in the top 6 measures for the quality performance category score) as long as the measure has the required case minimum, data completeness, and has a performance rate greater than zero, because we believed these qualities would allow us to include the measure in future benchmark development (81 FR 28255). Although we received public comments on this policy, responded to those comments, and reiterated this proposal in the CY 2017 Quality Payment Program final rule (81 FR 77292), we would like to clarify that our policy to assign measure bonus points for high priority measures, even if the measure's achievement points are not included in the total measure achievement points for calculating the quality performance category percent score, as long as the measure has the required case minimum, data completeness, and has a performance rate greater than zero, applies beginning with the transition year. We propose to amend § 414.1380(b)(1)(xiii)(A) (which we propose to redesignate as § 414.1380(b)(1)(xiv)(A)) to state that measure bonus points may be included in the calculation of the quality performance category percent score regardless of whether the measure is included in the calculation of the total measure achievement points. We also propose a technical correction to the second sentence of that paragraph to state that to qualify for measure bonus points, each measure must be reported with sufficient case volume to meet the required case minimum, meet the required data completeness criteria, and

[7] In section II.C.7.a.(2)(c) of this proposed rule, we propose a new provision to be codified at § 414.1380(b)(1)(xiii), and in section II.C.7.a.(2)(i) of this proposed rule, we propose a new provision to be codified at § 414.1380(b)(1)(xvi). As a result, we propose as well that the remaining paragraphs be redesignated in order following the new provisions.

not have a zero percent performance rate.

TABLE 17—EXAMPLE CALCULATION OF THE QUALITY PERFORMANCE CATEGORY PERCENT SCORE FOR AN INDIVIDUAL FOR THE TRANSITION YEAR

	Measure achievement points	Measure bonus points *	Total available measure achievement points	Performance category percent score
Measure 1 (Outcome—required).	3	n/a	10	(measure achievement points from 6 measures + measure bonus points)/total available measure achievement points.
Measure 2	6	n/a	10	
Measure 3	6	n/a	10	
Measure 4	6	n/a	10	
Measure 5	6	n/a	10	
Measure 6 (High priority)	4	1	10	
Measure 7 (High priority)	3 (not included for achievement).	1	n/a	
Total	31	2	60	(31+2)/60 = 55%

* Assumes the measures meet the required case minimum, data completeness, and has performance greater than zero. Assumes no bonus points for end-to-end electronic submission. This example does not apply to CMS Web Interface Reporters because individuals are not able to submit data via that mechanism.

A group of 16 or more clinicians will also be automatically scored on the hospital readmission measure if they meet the case minimum. Table 18 illustrates an example of a group that submitted the 6 required quality measures, including an additional high priority measure, and received 3 measure achievement points for each submitted measure and the all-cause readmission measure.

TABLE 18—EXAMPLE CALCULATION OF THE QUALITY PERFORMANCE CATEGORY PERCENT SCORE FOR A GROUP OF 16 OR MORE CLINICIANS, NON-CMS WEB INTERFACE REPORTER FOR THE TRANSITION YEAR

	Measure achievement points	Measure bonus points *	Total available measure achievement points	Performance category percent score
Measure 1 (Outcome—required).	3	n/a	10	(measure achievement points from 7 measures + measure bonus points)/total available measure achievement points.
Measure 2 (High priority)	3	1	10	
Measure 3	3	n/a	10	
Measure 4	3	n/a	10	
Measure 5	3	n/a	10	
Measure 6	3	n/a	10	
Measure 7—(readmission measure with 200+ cases).	3	n/a	10	
Total	21	1	70	(21+1)/70 = 31.4%

* Assumes the measures meet the required case minimum, data completeness, and has performance greater than zero. Assumes no bonus points for end-to-end electronic submission.

In the CY 2017 Quality Payment Program final rule, we also finalized scoring policies specific to groups of 25 or more that submit their quality performance measures using the CMS Web Interface (81 FR 77278 through 77306).

Although we are not proposing to change the basic scoring system that we finalized in the CY 2017 Quality Payment Program final rule for the 2020 MIPS payment year, we are proposing several modifications to scoring the quality performance category, including adjusting scoring for measures that do not meet the data completeness criteria, adding a method for scoring measures submitted via multiple mechanisms, adding a method for scoring selected topped out measures, and adding a method for scoring improvement. We also note that in section II.C.7.a.(4) of this proposed rule, we are also proposing an additional option for facility-based scoring for the quality performance category.

(a) Quality Measure Benchmarks

We are not proposing to change the policies on benchmarking finalized in the CY 2017 Quality Payment Program final rule and codified at paragraphs (b)(1)(i) through (iii) of § 414.1380; however, we are proposing a technical correction to paragraphs (i) and (ii) to clarify that measure benchmark data are separated into decile categories based on percentile distribution, and that, other than using performance period data, performance period benchmarks are created in the same manner as historical benchmarks using decile categories based on a percentile distribution and that each benchmark must have a minimum of 20 individual clinicians or groups who reported on the measure meeting the data completeness requirement and case minimum case size criteria and performance greater than zero. We refer

readers to the discussion at 81 FR 77282 for more details on that policy.

We note that in section II.C.2.c. of this proposed rule, we are proposing to increase the low-volume threshold which, because we include MIPS eligible clinicians and comparable APMs that meet our benchmark criteria in our measure benchmarks, could have an impact on our MIPS benchmarks, specifically by reducing the number of individual eligible clinicians and groups that meet the definition of a MIPS eligible clinician and contribute to our benchmarks. Therefore, we seek feedback on whether we should broaden the criteria for creating our MIPS benchmarks to include PQRS and any data from MIPS, including voluntary reporters, that meet our benchmark performance, case minimum and data completeness criteria when creating our benchmarks.

In the CY 2017 Quality Payment Program final rule, we did not stratify benchmarks by practice characteristics, such as practice size, because we did not believe there was a compelling rationale for such an approach, and we believed that stratifying could have unintended negative consequences for the stability of the benchmarks, equity across practices, and quality of care for beneficiaries (81 FR 77282). However, we sought comment on any rationales for or against stratifying by practice size we may not have considered. We note that we do create separate benchmarks for each of the following submission mechanisms: EHR submission options; QCDR and qualified registry submission options; claims submission options; CMS Web Interface submission options; CMS-approved survey vendor for CAHPS for MIPS submission options; and administrative claims submission options (for measures derived from claims data, such as the all-cause hospital readmission measure) (81 FR 77282).

Several commenters who responded to our solicitation of comment in the final rule supported stratifying measure benchmarks by practice size because the commenters believed it would help small practices, which have limited resources compared to larger practices, and because quality measures may have characteristics that are less favorable to small groups. One commenter recommended that we stratify by practice size during the 5 years in which technical assistance is available. One commenter recommended that we develop criteria for determining when a benchmark should be stratified by group size, and another commenter recommended if we do not stratify benchmarks by practice size, we adjust MIPS payment adjustments for practice size. Several commenters recommended that we stratify benchmarks beyond practice size and include adjustments for disease severity and socioeconomic status of patients, specialty or sub-specialty, geographic region, and/or site of service. One commenter specifically suggested that we use peer comparison groups when establishing measure benchmarks.

After consideration of the comments we received, we are not proposing to change our policies related to stratifying benchmarks by practice size for the 2020 MIPS payment year. For many measures, the benchmarks may not need stratification as they are only meaningful to certain specialties and only expected to be submitted by those certain specialists. We would like to further clarify that in the majority of instances our current benchmarking approach only compares like clinicians to like clinicians. We continue to believe that stratifying by practice size could have unintended negative consequences for the stability of the benchmarks, equity across practices, and quality of care for beneficiaries. However, we seek comment on methods by which we could stratify benchmarks, while maintaining reliability and stability of the benchmarks, to use in developing future rulemaking for future performance and payment years. Specifically, we seek comment on methods for stratifying benchmarks by specialty or by place of service. We also request comment on specific criteria to consider for stratifying measures, such as how we should stratify submissions by multi-specialty practices or by practices that operate in multiple places of service.

(b) Assigning Points Based on Achievement

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1380(b)(1) that a MIPS quality measure must have a measure benchmark to be scored based on performance. MIPS quality measures that do not have a benchmark (for example, because fewer than 20 MIPS eligible clinicians or groups submitted data that met our criteria to create a reliable benchmark) will not be scored based on performance (81 FR 77286). We are not proposing any changes to this policy, but we are proposing a technical correction to the regulatory text at § 414.1380(b)(1) to delete the term ''MIPS'' before ''quality measure'' in third sentence of that paragraph and to delete the term MIPS before ''quality measures'' in the fourth sentence of that paragraph because this policy applies to all quality measures, including the measures finalized for the MIPS program and the quality measures submitted through a QCDR that have been approved for MIPS.

We are also not proposing to change the policies to score quality measure performance using a percentile distribution, separated by decile categories and assign partial points based on the percentile distribution finalized in the CY 2017 Quality Payment Program final rule and codified at paragraphs (b)(1)(ix), (x), and (xi) of § 414.1380; however, we propose a technical correction to paragraph (ix) to clarify that measures are scored against measure benchmarks. We refer readers to the discussion at 81 FR 77286 for more details on those policies.

For illustration, Table 19 provides an example of assigning points for performance based on benchmarks using a percentile distribution, separated by decile categories. The example is of the benchmarks for Measure 130 Documentation of Current Medications in the Medical Record, which is based on our 2015 benchmark file for the 2017 MIPS performance period.

TABLE 19—EXAMPLE OF ASSIGNING POINTS FOR PERFORMANCE BASED ON A BENCHMARK, SEPARATED BY DECILES

Submission mechanism	Measure ID #130 (documentation of current medications in the medical record) *		
	Claims performance benchmark	EHR performance benchmark	Registry/QCDR benchmark
Decile 1 or 2 (3 points)	<96.11	<76.59	<61.27
Decile 3 (3.0–3.9 points)	96.11–98.73	76.59–87.88	61.27–82.11
Decile 4 (4.0–4.9 points)	98.74–99.64	87.89–92.73	82.12–91.71
Decile 5 (5.0–5.9 points)	99.65–99.99	92.74–95.35	91.72–96.86

TABLE 19—EXAMPLE OF ASSIGNING POINTS FOR PERFORMANCE BASED ON A BENCHMARK, SEPARATED BY DECILES—Continued

Submission mechanism	Measure ID #130 (documentation of current medications in the medical record) *		
	Claims performance benchmark	EHR performance benchmark	Registry/QCDR benchmark
Decile 6 (6.0–6.9 points)	—	95.36 –97.08	96.87–99.30
Decile 7 (7.0–7.9 points)	—	97.09–98.27	99.31 –99.99
Decile 8 (8.0–8.9 points)	—	98.28–99.12	—
Decile 9 (9.0–9.9 points)	—	99.13–99.75	—
Decile 10 (10 points)	100	>= 99.76	100

* Based on our historical benchmark file for the 2017 MIPS performance period.

In Table 19, the cells with ''—'' represent where there is a cluster at the top of benchmark distribution. For example, for the claims benchmark, over 50 percent of the MIPS eligible clinicians submitting that measure had a performance rate of 100 percent based on 2015 PQRS data. Because of the cluster, clinicians who are at the 6, 7, 8, and 9th decile all would have performance rates of 100 percent and would all receive a score of 10 points, indicated by dashes for those deciles. Based on this clustered distribution, those clinicians with performance of 99.99 percent fall into decile 5 and receive points in the range from 5.0 to 5.9 points. For this measure, the benchmark for each submission mechanism is topped out.

We note that for quality measures for which baseline period data is available, we will publish the numerical baseline period benchmarks with deciles prior to the start of the performance period (or as soon as possible thereafter) (81 FR 77282). For quality measures for which there is no comparable data from the baseline period, we will publish the numerical performance period benchmarks after the end of the performance period (81 FR 77282). We will also publish further explanation of how we calculate partial points at *qpp.cms.gov*.

(i) Floor for Scored Quality Measures

For the 2017 MIPS performance period, we also finalized at § 414.1380(b)(1) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable), such that MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements (81 FR 77286 through 77287). Likewise, for measures without a benchmark based on the baseline period, we stated that we would continue to assign between 3 and 10 measure achievement points for performance years after the first transition year because it would help to ensure that the MIPS eligible clinicians are protected from a poor performance score that they would not be able to anticipate (81 FR 77282; 81 FR 77287). For measures with benchmarks based on the baseline period, we stated the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years (81 FR 77286 through 77287).

For the 2018 MIPS performance period, we propose to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend § 414.1380(b)(1) accordingly. We refer readers to section II.C.7.a.(2)(h)(ii) of this rule, for our proposal to score measures in the CMS Web Interface for the Quality Payment Program for which performance is below the 30th percentile. We will revisit the 3-point floor for such measures again in future rulemaking.

We invite public comment on this proposal to again apply this 3-point floor for quality measures that can be reliably scored against a baseline benchmark in the 2018 MIPS performance period.

(ii) Additional Policies for the CAHPS for MIPS Measure Score

In the CY 2017 Quality Payment Program final rule, we finalized a policy for the CAHPS for MIPS measure, such that each Summary Survey Measure (SSM) will have an individual benchmark, that we will score each SSM individually and compare it against the benchmark to establish the number of points, and the CAHPS score will be the average number of points across SSMs (81 FR 77284).

As described in section II.C.6.b.(3)(a)(iii) of this proposed rule, we are proposing to remove two SSMs from the CAHPS for MIPS survey, which would result in the collection of 10 SSMs in the CAHPS for MIPS survey. Eight of those 10 SSMs have had high reliability for scoring in prior years, or reliability is expected to improve for the revised version of the measure, and they also represent elements of patient experience for which we can measure the effect one practice has compared to other practices participating in MIPS. The ''Health Status and Functional Status'' SSM, however, assesses underlying characteristics of a group's patient population characteristics and is less of a reflection of patient experience of care with the group. Moreover, to the extent that health and functional status reflects experience with the practice, case-mix adjustment is not sufficient to separate how much of the score is due to patient experience versus due to aspects of the underlying health of patients. The ''Access to Specialists'' SSM has low reliability; historically it has had small sample sizes, and therefore, the majority of groups do not achieve adequate reliability, which means there is limited ability to distinguish between practices' performance.

For these reasons, we propose not to score the ''Health Status and Functional Status'' SSM and the ''Access to Specialists'' SSM beginning with the 2018 MIPS performance period. Despite not being suitable for scoring, both SSMs provide important information about patient care. Qualitative work suggests that ''Access to Specialists'' is a critical issue for Medicare FFS beneficiaries. The survey is also a useful tool for assessing beneficiaries' self-reported health status and functional status, even if this measure is not used for scoring practices' care experiences. Therefore, we believe that continued collection of the data for these two SSMs is appropriate even though we do not propose to score them.

Other than these two SSMs, we propose to score the remaining 8 SSMs because they have had high reliability for scoring in prior years, or reliability is expected to improve for the revised version of the measure, and they also

represent elements of patient experience for which we can measure the effect one practice has compared to other practices participating in MIPS. Table 20 summarizes the proposed SSMs included in the CAHPS for MIPS survey and illustrates application of our proposal to score only 8 measures.

TABLE 20—PROPOSED SSM FOR CAHPS FOR MIPS SCORING

Summary survey measure	Proposed for inclusion in the CAHPS for MIPS *survey*?	Proposed for inclusion in CAHPS for MIPS *scoring*?
Getting Timely Care, Appointments, and Information	Yes	Yes.
How Well Providers Communicate	Yes	Yes.
Patient's Rating of Provider	Yes	Yes.
Health Promotion & Education	Yes	Yes.
Shared Decision Making	Yes	Yes.
Stewardship of Patient Resources	Yes	Yes.
Courteous and Helpful Office Staff	Yes	Yes.
Care Coordination	Yes	Yes.
Health Status and Functional Status	Yes	No.
Access to Specialists	Yes	No.

We invite comment on our proposal not to score the ''Health Status and Functional Status'' and ''Access to Specialists'' SSMs beginning with the 2018 MIPS performance period.

We note that in section II.C.6.g.(3)(b)(i)(A) of this proposed rule, we are proposing to add the CAHPS for ACOs survey as an available measure for calculating the MIPS APM score for the Shared Savings Program and Next Generation ACO Model. We refer readers participating in ACOs to section II.C.6.g.(3)(b) of this proposed rule for the CAHPS for ACOs scoring methodology.

(c) Identifying and Assigning Measure Achievement Points for Topped Out Measures

Section 1848(q)(3)(B) of the Act requires that, in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. We finalized in the CY 2017 Quality Payment Program final rule that we would identify topped out process measures as those with a median performance rate of 95 percent or higher (81 FR 77286). For non-process measures we finalized a topped out definition similar to the definition used in the Hospital VBP Program: Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors (81 FR 77286). When a measure is topped out, a large majority of clinicians submitting the measure performs at or very near the top of the distribution; therefore, there is little or no room for the majority of MIPS eligible clinicians who submit the measure to improve. We understand that every measure we have identified as topped out may offer room for improvement for some MIPS eligible clinicians; however, we believe asking clinicians to submit measures that we have identified as topped out and measures for which they already excel is an unnecessary burden that does not add value or improve beneficiary outcomes.

Based on 2015 historic benchmark data,[8] approximately 45 percent of the quality measure benchmarks currently meet the definition of topped out, with some submission mechanisms having a higher percent of topped out measures than others. Approximately 70 percent of claims measures are topped out, 10 percent of EHR measures are topped out, and 45 percent of registry/QCDR measures are topped out.

In the CY 2017 Quality Payment Program final rule, we finalized that for the 2019 MIPS payment year, we would score topped out quality measures in the same manner as other measures (81 FR 77286). We finalized that we would not modify the benchmark methodology for topped out measures for the first year that the measure has been identified as topped out, but that we would modify the benchmark methodology for topped out measures beginning with the 2020 MIPS payment year, provided that it is the second year the measure has been identified as topped out. As described in detail later in this section, we are proposing a phased in approach to apply special scoring to topped out measures, beginning with the 2018 MIPS performance period (2020 MIPS payment year), rather than modifying the benchmark methodology for topped out measures as indicated in the CY 2017 Quality Payment Program final rule.

[8] The topped out determination is calculated on historic performance data and the percentage of topped out measures may change when evaluated for the most applicable annual period.

In the CY 2017 Quality Payment Program final rule, we sought comment on how topped out measures should be scored provided that it is the second year the measure has been identified as topped out (81 FR 77286). We suggested three possible options: (1) Score the measures using a mid-cluster approach; (2) remove topped out measures; or (3) apply a flat percentage in building the benchmarks for topped out measures. Flat percentages assign points based directly on the percentage of performance rather than by a percentile distribution by decile. Flat-rate would provide high scores to virtually all clinicians submitting the measure because performance rates tend to be high. Cluster-based benchmarks for topped out measures are based on a percentile distribution, but because many submitters are clustered at the top of performance, there can be large drops in points assigned for relatively small differences in performance. The current top of the cluster approach can result in many clinicians receiving 10 points. A mid-cluster approach would limit the maximum number of points a topped out measure can achieve based on how clustered the score are, and could still result in large drops, although less than with the top of the cluster approach, in points assigned for relatively small differences in performance. We also noted in the CY 2017 Quality Payment Program final rule that we anticipate removing topped out measures over time and sought comment on what point in time we should remove topped out measures from MIPS (81 FR 77286). The comments and our proposed policy for removing topped out measures are described in section II.C.6.c.(2) of this proposed rule.

In response to our request for comment in the CY 2017 Quality Payment Program final rule, a few

commenters believed that we should not score topped out measures differently from other measures because commenters believed changing the scoring could reduce quality, add complexity to the program, and reduce incentives to participate in MIPS. Several commenters recommended that if we do score topped out measures differently, we use flat percentages rather than cluster-based benchmarks, with a few commenters noting that using flat percentages could help ensure those with high performance on a measure are not penalized as low performers and another noting that allowing high scorers to earn maximum or near maximum points is similar to the approach in the Shared Savings Program. A few commenters recommended that we publish information about topped out and potentially topped out measures prior to the performance period to allow clinicians time to adjust their reporting strategies, with one commenter noting that improvement may be rewarded in addition to achievement. One commenter recommended pushing back the baseline performance period for identifying topped out measures to the 2018 MIPS performance period because in the transition year it is unclear how many eligible clinicians will be reporting at different times and for what period they will report.

As described in section II.C.6.c.(2) of this proposed rule, we are proposing a lifecycle for topped out measures by which, after a measure benchmark is identified as topped out in the published benchmark for 2 years, in the third consecutive year it is identified as topped out it will be considered for removal through notice-and-comment rulemaking or the QCDR approval process and may be removed from the benchmark list in the fourth year, subject to the phased in approach described in section II.C.6.c.(2) of this proposed rule.

As part of the lifecycle for topped out measures, we also propose in this section II.C.7.a.(2)(c) of this proposed rule, a method to phase in special scoring for topped out measure benchmarks starting with the 2018 MIPS performance period, provided that is the second consecutive year the measure benchmark is identified as topped out in the benchmarks published for the performance period. This special scoring would not apply to measures in the CMS Web Interface, as explained later in this section. The phased-in approach described in this section represents our first step in methodically implementing special scoring for topped out measures.

We are not proposing to remove topped out measures for the 2018 MIPS performance period because we recognize that there are currently a large number of topped out measures and removing them may impact the ability of some MIPS eligible clinicians to submit 6 measures and may impact some specialties more than others. We note, however, that as described in section II.C.6.c.(2) of this proposed rule, we are proposing a timeline for removing topped out measures in future years. We believe this provides MIPS eligible clinicians the ability to anticipate and plan for the removal of specific topped out measures, while providing measure developers time to develop new measures.

We note that because we create a separate benchmark for each submission mechanism available for a measure, a benchmark for one submission mechanism for the measure may be identified as topped out while another submission mechanism's benchmark may not be topped out. The topped out designation and special scoring apply only to the specific benchmark that is topped out, not necessarily every benchmark for a measure. For example, the benchmark for the claims submission mechanism may be topped out for a measure, but the benchmark for the EHR submission mechanisms for that same measure may not be topped out. In this case, the topped out scoring would only apply to measures submitted via the claims submission mechanism, which has the topped out benchmark. We also describe in section II.C.6.c.(2) of this proposed rule that, similarly, only the submission mechanism that is topped out for the measure would be removed.

We propose to cap the score of topped out measures at 6 measure achievement points. We are proposing a 6-point cap for multiple reasons. First, we believe applying a cap to the current method of scoring a measure against a benchmark is a simple approach that can easily be predicted by clinicians. Second, the cap will create incentives for clinicians to submit other measures for which they can improve and earn future improvement points. Third, considering our proposed topped out measure lifecycle, we believe this cap would only be used for a few years and the simplicity of a cap on the current benchmarks would outweigh the cluster-based options or applying a cap on benchmarks based on flat-percentage, which are more complicated. The rationale for a 6-point cap is that 6 points is the median score for any measure as it represents the start of the 6th decile for performance and represents the spot between the bottom 5 deciles and start of the top 5 deciles.

We believe this proposed capped scoring methodology will incentivize MIPS eligible clinicians to begin submitting non-topped out measures without performing below the median score. This methodology also would not impact scoring for those MIPS eligible clinicians that do not perform near the top of the measure and therefore have significant room to improve on the measure. We may also consider lowering the cap below 6 points in future years, especially if we remove the 3-point floor for performance in future years.

We note that although we are proposing a new methodology for assigning measure achievement points for topped out measures, we are not changing the policy for awarding measure bonus points for topped out measures. Topped out measures will still be eligible for measure bonus points if they meet the required criteria. We refer readers to sections II.C.7.a.(2)(f) and II.C.7.a.(2)(g) of this proposed rule for more information about measure bonus points.

We request comments on our proposal to score topped out measures differently by applying a 6-point cap, provided it is the second consecutive year the measure is identified as topped out. Specifically, we seek feedback on whether 6 points is the appropriate cap or whether we should consider another value. We also seek comment on other possible options for scoring topped out measures that would meet our policy goals to encourage clinicians to begin to submit measures that are not topped out while also providing stability for MIPS eligible clinicians.

While we believe it is important to score topped out measures differently because they could have a disproportionate impact on the scores for certain MIPS eligible clinicians and topped out measures provide little room for improvement for the majority of MIPS eligible clinicians who submit them, we also recognize that numerous measure benchmarks are currently identified as topped out and special scoring for topped out measures could impact some specialties more than others. Therefore, we considered ways to phase in special scoring for topped out measures in a way that will begin to apply special scoring, but would not overwhelm any one specialty and would also provide additional time to evaluate the impact of topped out measures before implementing it for all topped out measures, while also beginning to encourage submission of measures that are not topped out.

We believe the best way to accomplish this is by applying special topped out scoring to a select number of measures for the 2018 performance period and to then apply the special topped out scoring to all topped out measures for the 2019 performance period, provided it is the second consecutive year the measure is topped out. We believe this approach allows us time to further evaluate the impact of topped out measures and allows for a methodical way to phase in topped out scoring.

We identified measures we believe should be scored with the special topped out scoring for the 2018 performance period by using the following set criteria, which are only intended as a way to phase in our topped-out measure policy for selected measures and are not intended to be criteria for use in future policies:

- Measure is topped out and there is no difference in performance between decile 3 through decile 10. We applied this limitation because, based on historical data, there is no room for improvement for over 80 percent of MIPS eligible clinicians that reported on these measures.
- Process measures only because we want to continue to encourage reporting on high priority outcome measures, and the small subset of structure measures was confined to only three specialties.
- MIPS measures only (which does not include measures that can only be reported through a QCDR) given that QCDR measures go through a separate process for approval and because we want to encourage use of QCDRs required by section 1848(q)(1)(E) of the Act.
- Measure is topped out for all mechanisms by which the measure can be submitted. Because we create a separate benchmark for each submission mechanism available for a measure, a benchmark for one submission mechanism for the measure may be identified as topped out while another submission mechanism's benchmark may not be topped out. For example, the benchmark for the claims submission mechanism may be topped out for a measure, but the benchmark for the EHR submission mechanisms for that same measure may not be topped out. We decided to limit our criteria to only measures that were topped out for all measures for simplicity and to avoid confusion about what scoring is applied to a measure.
- Measure is in a specialty set with at least 10 measures, because 2 measures in the pathology specialty set, which only has 8 measures total would have been included.

Applying these criteria results in the 6 measures as listed in Table 21.

TABLE 21—TOPPED OUT MEASURES PROPOSED FOR SPECIAL SCORING FOR THE 2018 MIPS PERFORMANCE PERIOD

Measure name	Measure ID	Measure type	Topped out for all submission mechanisms	Specialty set
Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin.	21	Process	Yes	General Surgery, Orthopedic Surgery, Otolaryngology, Thoracic Surgery, Plastic Surgery.
Melanoma: Overutilization of Imaging Studies in Melanoma.	224	Process	Yes	Dermatology.
Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).	23	Process	Yes	General Surgery, Orthopedic Surgery, Otolaryngology, Thoracic Surgery, Plastic Surgery.
Image Confirmation of Successful Excision of Image—Localized Breast Lesion.	262	Process	Yes	n/a.
Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computerized Tomography (CT) Imaging Description.	359	Process	Yes	Diagnostic Radiology.
Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy.	52	Process	Yes	n/a.

We propose to apply the special topped out scoring method that we finalize for the 2018 performance period to only the 6 measures in Table 21 for the 2018 performance period, provided they are again identified as topped out in the benchmarks for the 2018 performance period. If these measures are not identified as topped out in the benchmarks published for the 2018 performance period, they will not be scored differently because they would not be topped out for a second consecutive year.

We seek comment on our proposal to apply special topped out scoring only to the 6 measures identified in Table 21 for the 2018 performance period.

Starting with the 2019 performance period, we propose to apply the special topped out scoring method to all topped out measures, provided it is the second (or more) consecutive year the measure is identified as topped out. We seek comment on our proposal to apply special topped out scoring to all topped out measures, provided it is the second (or more) consecutive year the measure is identified as topped out.

We illustrate the lifecycle for scoring and removing topped out measures based on our proposals as follows:

- *Year 1:* Measure benchmarks are identified as topped out, which in this example would be in the benchmarks published for the 2017 MIPS performance period.
- *Year 2:* Measure benchmarks are identified as topped out, which in this example would be in the benchmarks published for the 2018 MIPS performance period. Measures identified in Table 21 have special scoring applied, provided they are identified as topped out for the 2018 MIPS performance period, meaning it is the second consecutive year they are identified as topped out.
- *Year 3:* Measure benchmarks are identified as topped out in the benchmarks published for the 2019 MIPS performance period. All measure benchmarks identified as topped out for the second (or more) consecutive year have special scoring applied for the 2019 MIPS performance period. In Year 3 we would also consider removal of the select set of topped out measures identified in Table 21, through notice and comment rulemaking, provided they are identified as topped out during the previous two (or more) consecutive

years. In our example, Year 3 would be the 2019 performance period.

- *Year 4:* Measure benchmarks are identified as topped out in the benchmarks published for the 2020 MIPS performance period. Measure benchmarks identified as topped out for a second (or more) consecutive year continue to have special scoring applied. Topped out measures finalized for removal for the 2020 MIPS performance period are no longer available for reporting.

An example of applying the proposed scoring cap compared to scoring applied for the 2017 MIPS performance period is provided in Table 22.

TABLE 22—PROPOSED SCORING FOR TOPPED OUT MEASURES* STARTING IN THE CY 2018 MIPS PERFORMANCE PERIOD COMPARED TO THE TRANSITION YEAR SCORING

Scoring policy	Measure 1 (topped out)	Measure 2 (topped out)	Measure 3 (topped out)	Measure 4 (topped out)	Measure 5 (not topped out)	Measure 6 (not topped out)	Quality Cate-gory Percent Score*
2017 MIPS performance period Scoring.	10 measure achievement points.	10 measure achievement points.	10 measure achievement points.	4 measure achievement points (did not get max score).	10 measure achievement points.	5 measure achievement points.	49/60 = 81.67%.
Proposed Capped Scoring applied.	6 measure achievement points.	6 measure achievement points.	6 measure achievement points.	4 measure achievement points.	10 measure achievement points.	5 measure achievement points.	37/60 = 61.67%.
Notes	Topped out measures scored with 6-point measure achievement point cap. Cap does not impact score if the MIPS eligible clinician's score is below the cap.				Still possible to earn maximum measure achievement points on the non-topped out measures.		

*This example would only apply to the 6 measures identified in Table 21 for the CY 2018 MIPS Performance Period. This example also excludes bonus points and improvement scoring proposed in section II.C.7.a.(2)(i) of this proposed rule.

Together the proposed policies for phasing in capped scoring and removing topped out measures are intended to provide an incentive for MIPS eligible clinicians to begin to submit measures that are not topped out while also providing stability by allowing MIPS eligible clinicians who have few alternative measures to continue to receive standard scoring for most topped out measures for an additional year, and not perform below the median score for those 6 measures that receive special scoring. It also provides MIPS eligible clinicians the ability to anticipate and plan for the removal of specific topped out measures, while providing measure developers time to develop new measures.

We propose to add a new paragraph at § 414.1380(b)(1)(xiii) to codify our proposal for the lifecycle for removing topped out measures.

We also propose to add at § 414.1380(b)(1)(xiii)(A) that for the 2018 MIPS performance period, the 6 measures identified in Table 21 will receive a maximum of 6 measure achievement points, provided that the measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. We also propose to add at § 414.1380(b)(1)(xiii)(B) that beginning with the 2019 MIPS performance period, measure benchmarks, except for measures in the CMS Web Interface, that are identified as topped out for two 2 or more consecutive years will receive a maximum of 6 measure achievement points in the second consecutive year it is identified as topped out, and beyond. We specifically seek comment on whether the proposed policy to cap the score of topped out measures beginning with the 2019 performance period should apply to SSMs in the CAHPS for MIPS survey measure or whether there is another alternative policy that could be applied for the CAHPS for MIPS survey measure due to high, unvarying performance within the SSM. We note that we would like to encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

We stated in the CY 2017 Quality Payment Program final rule that we do not believe it would be appropriate to remove topped out measures from the CMS Web Interface for the Quality Payment Program because the CMS Web Interface measures are used in MIPS and in APMs such as the Shared Savings Program and because we have aligned policies, where possible, with the Shared Savings Program, such as using the Shared Savings Program benchmarks for the CMS Web Interface measures (81 FR 77285). In the CY 2017 Quality Payment Program final rule, we also finalized that MIPS eligible clinicians submitting via the CMS Web Interface must submit all measures included in the CMS Web Interface (81 FR 77116). Thus, if a CMS Web Interface measure is topped out, the CMS Web Interface submitter cannot select other measures. Because of the lack of ability to select measures, we are not proposing to apply a special scoring adjustment to topped out measures for CMS Web Interface for the Quality Payment Program.

Additionally, because the Shared Savings Program incorporates a methodology for measures with high performance into the benchmark, we do not believe capping benchmarks from the CMS Web Interface for the Quality Payment Program is appropriate. We finalized in the CY 2017 Quality Payment Program final rule at § 414.1380(b)(1)(ii)(A) to use benchmarks from the corresponding reporting year of the Shared Savings Program. The Shared Savings Program adjusts some benchmarks to a flat percentage when the 60th percentile is equal to or greater than 80.00 percent for individual measures (78 FR 74759 through 74763), and, for other measures, benchmarks are set using flat percentages when the 90th percentile for a measure are equal to or greater than 95.00 percent (79 FR 67925). Thus, we are not proposing to apply the topped out measure cap to measures in the CMS Web Interface for the Quality Payment Program.

We seek comment on this proposal not to apply the topped out measure cap to measures in the CMS Web Interface for the Quality Payment Program.

(d) Case Minimum Requirements and Measure Reliability and Validity

To help ensure reliable measurement, in the CY 2017 Quality Payment Program final rule (81 FR 77288), we finalized a 20-case minimum for all quality measures except the all-cause hospital readmission measure. For the all-cause hospital readmission measure, we finalized in the CY 2017 Quality Payment Program final rule a 200-case minimum and finalized to apply the all-cause hospital readmission measure only to groups of 16 or more clinicians that meet the 200-case minimum requirement (81 FR 77288).

We are not proposing any changes to these policies.

For the 2019 MIPS payment year, we finalized in the CY 2017 Quality Payment Program final rule that if the measure is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement, the measure would receive a score of 3 points (81 FR 77288 through 77289). We identified two classes of measures for the transition year. Class [9] 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum requirement, and meet the data completeness standard. We finalized that Class 1 measures would receive 3 to 10 points based on performance compared to the benchmark (81 FR 77289). Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark, do not have at least 20 cases, or the submitted measure does not meet data completeness criteria. We finalized that Class 2 measures, which do not include measures submitted with the CMS Web Interface or administrative claims-based measures, receive 3 points (81 FR 77289).

We propose to maintain the policy to assign 3 points for measures that are submitted but do not meet the required case minimum or does not have a benchmark for the 2020 MIPS payment year and amend § 414.1380(b)(1)(vii) accordingly.

We also propose a change to the policy for scoring measures that do not meet the data completeness requirement for the 2020 MIPS payment year.

To encourage complete reporting, we are proposing that in the 2020 MIPS payment year, measures that do not meet data completeness standards will receive 1 point instead of the 3 points that were awarded in the 2019 MIPS payment year. We propose lowering the point floor to 1 for measures that do not meet data completeness standards for several reasons. First, we want to encourage complete reporting because data completeness is needed to reliably measure quality. Second, unlike case minimum and availability of a benchmark, data completeness is within the direct control of the MIPS eligible clinician. In the future, we intend that measures that do not meet the completeness criteria will receive zero points; however, we believe that during the second year of transitioning to MIPS, clinicians should continue to receive at least 1 measure achievement point for any submitted measure, even if the measure does not meet the data completeness standards.

We are concerned, however, that data completeness may be harder to achieve for small practices. For example, small practices tend to have small case volume and missing one or two cases could cause the MIPS eligible clinician to miss the data completeness standard as each case may represent multiple percentage points for data completeness. For example, for a small practice with only 20 cases for a measure, each case is worth 5 percentage points, and if they miss reporting just 11 or more cases, they would fail to meet the data completeness threshold, whereas for a practice with 200 cases, each case is worth 0.5 percentage points towards data completeness and the practice would have to miss more than 100 cases to fail to meet the data completeness criteria. Applying 1 point for missing data completeness based on missing a relatively small number of cases could disadvantage these clinicians, who may have additional burdens for reporting in MIPS, although we also recognize that failing to report on 10 or more patients is undesirable. In addition, we know that many small practices may have less experience with submitting quality performance category data and may not yet have systems in place to ensure they can meet the data completeness criteria. Thus, we are also proposing an exception to the proposed policy for measures submitted by small practices, as defined in § 414.1305. We propose that these clinicians would continue to receive 3 points for measures that do not meet data completeness.

Therefore, we propose to revise Class 2 measures to include only measures that cannot be scored based on performance because they do not have a benchmark or do not have at least 20 cases. We also propose to create Class 3 measures, which are measures that do not meet the data completeness requirement. We propose that the revised Class 2 measure would continue to receive 3 points. The proposed Class 3 measures would receive 1 point, except if the measure is submitted by a small practice in which case the Class 3 measure would receive 3 points. However, consistent with the policy finalized in the CY 2017 Quality Payment Program final rule, these policies for Class 2 and Class 3 measures would not apply to measures submitted with the CMS Web Interface or administrative claims-based measures. A summary of the proposals is provided in Table 23.

TABLE 23—QUALITY PERFORMANCE CATEGORY: SCORING MEASURES BASED ON PERFORMANCE

Measure type	Description in transition year	Scoring rules in 2017 MIPS performance period	Description proposed for 2018 MIPS performance period	Proposed for 2018 MIPS performance period
Class 1	Measures that can be scored based on performance. Measures that were submitted or calculated that met the following criteria: (1) The measure has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 50 percent.)	3 to 10 points based on performance compared to the benchmark.	Same as transition year	Same as transition year. 3 to 10 points based on performance compared to the benchmark.

[9] References to ''Classes'' of measures in this section II.C.7.a.(2)(d) are intended only to characterize the measures for ease of discussion.

TABLE 23—QUALITY PERFORMANCE CATEGORY: SCORING MEASURES BASED ON PERFORMANCE—Continued

Measure type	Description in transition year	Scoring rules in 2017 MIPS performance period	Description proposed for 2018 MIPS performance period	Proposed for 2018 MIPS performance period
Class 2	Measures that cannot be scored based on performance. Measures that were submitted, but fail to meet one of the Class 1 criteria. The measure either (1) does not have a benchmark, (2) does not have at least 20 cases, or (3) does not meet data completeness criteria.	3 points ..... * This Class 2 measure policy does not apply to CMS Web Interface measures and administrative claims based measures.	Measures that were submitted and meet data completeness, but does not have one or both of the following: (1) a benchmark (2) at least 20 cases	3 points *This Class 2 measure policy would not apply to CMS Web Interface measures and administrative claims based measures.
Class 3	n/a	n/a	Measures that were submitted, but do not meet data completeness criteria, regardless of whether they have a benchmark or meet the case minimum.	1 point except for small practices, which would receive 3 points. *This Class 3 measure policy would not apply to CMS Web Interface measures and administrative claims based measures.

We propose to amend § 414.1380(b)(1)(vii) to assign 3 points for measures that do not meet the case minimum or do not have a benchmark in the 2020 MIPS payment year, and to assign 1 point for measures that do not meet data completeness requirements, unless the measure is submitted by a small practice, in which case it would receive 3 points.

We invite comment on our proposal to assign 1 point to measures that do not meet data completeness criteria, with an exception for measures submitted by small practices.

We are not proposing to change the methodology we use to score measures submitted via the CMS Web Interface that do not meet the case minimum, do not have a benchmark, or do not meet the data completeness requirement finalized in the CY 2017 Quality Payment Program final rule and codified at paragraph (b)(1)(viii) of § 414.1380. However, we note that as described in section II.C.7.a.(2)(h)(ii) of this proposed rule, we are proposing to add that CMS Web Interface measures with a benchmark that are redesignated from pay for performance to pay for reporting by the Shared Savings Program will not be scored. We refer readers to the discussion at 81 FR 77288 for more details on our previously finalized policy.

We are also not proposing any changes to the policy to not include administrative claims measures in the quality performance category percent score if the case minimum is not met or if the measure does not have a benchmark finalized in the CY 2017 Quality Payment Program final rule and codified at paragraph (b)(1)(viii) of § 414.1380. We refer readers to the discussion at 81 FR 77288 for more details on that policy.

To clarify the exclusion of measures submitted via the CMS Web Interface and based on administrative claims from the policy changes proposed to be codified at paragraph (b)(1)(vii) previously, we are amending paragraph (b)(1)(vii) to make it subject to paragraph (b)(1)(viii), which codifies the exclusion.

(e) Scoring for MIPS Eligible Clinician That Do Not Meet Quality Performance Category Criteria

In the CY 2017 Quality Payment Program final rule, we finalized that MIPS eligible clinicians who fail to submit a measure that is required to satisfy the quality performance category submission criteria would receive zero points for that measure (81 FR 77291). For each required measure that is not submitted, a MIPS eligible clinician would receive zero points out of 10. For example, if a MIPS eligible clinician had 6 measures available and applicable but submitted only 4 measures, the MIPS eligible clinician would be assigned zero out of 10 measure achievement points for the 2 missing measures, which would be calculated into their performance category percent score.

We are not proposing any changes to the policy to assign zero points for failing to submit a measure that is required in this proposed rule.

In the CY 2017 Quality Payment Program final rule, we also finalized implementation of a validation process for claims and registry submissions to validate whether MIPS eligible clinicians have 6 applicable and available measures, whether an outcome measure is available or whether another high priority measure is available if an outcome measure is not available (81 FR 77290 through 77291).

We are not proposing any changes to apply a process to validate whether MIPS eligible clinicians that submit measures via claims and registry submissions have measures available and applicable. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77290), we did not intend to establish a validation process for QCDRs because we expect that MIPS eligible clinicians that enroll in QCDRs will have sufficient meaningful measures to meet the quality performance category criteria (81 FR 77290 through 77291). We do not propose any changes to this policy.

We also stated that if a MIPS eligible clinician did not have 6 measures relevant within their EHR to meet the full specialty set requirements or meet the requirement to submit 6 measures, the MIPS eligible clinician should select a different submission mechanism to meet the quality performance category requirements and should work with their EHR vendors to incorporate applicable measures as feasible (81 FR 77290 through 77291). Under our proposals in section II.C.6.a.(1) of this proposed rule to allow measures to be submitted and scored via multiple mechanisms within a performance category, we anticipate that MIPS

eligible clinicians that submit fewer than 6 measures via EHR will have sufficient additional measures available via a combination of submission mechanisms to submit the measures required to meet the quality performance category criteria. For example, the MIPS eligible clinician could submit 2 measures via EHR and supplement that with 4 measures via QCDR or registry.

Therefore, given our proposal to score multiple mechanisms, if a MIPS eligible clinician submits any quality measures via EHR or QCDR, we would not conduct a validation process because we expect these MIPS eligible clinicians to have sufficient measures available to meet the quality performance category requirements.

Given our proposal in section II.C.7.a.(2)(h) of this proposed rule to score measures submitted via multiple mechanisms, we propose to validate the availability and applicability of measures only if a MIPS eligible clinician submits via claims submission options only, registry submission options only, or a combination of claims and registry submission options. In these cases, we propose that we will apply the validation process to determine if other measures are available and applicable broadly across claims and registry submission options. We will not check if there are measures available via EHR or QCDR submission options for these reporters. We note that groups cannot report via claims and therefore groups and virtual groups will only have validation applied across registries. We would validate the availability and applicability of a measure through a clinically related measure analysis based on patient type, procedure, or clinical action associated with the measure specifications. For us to recognize fewer than 6 measures, an individual MIPS eligible clinician must submit exclusively using claims or qualified registries or a combination of the two, and a group or virtual group must submit exclusively using qualified registries. Given our proposal in section II.C.7.a.(2)(h) of this proposed rule to score measures submitted via multiple mechanisms, validation will be conducted first by applying the clinically related measure analysis for the individual measure and then, to the extent technically feasible, validation will be applied to check for available measures available via both claims and registries.

We recognize that in extremely rare instances there may be a MIPS eligible clinician who may not have available and applicable quality measures. For example, a subspecialist who focuses on a very targeted clinical area may not have any measures available. However, in many cases, the clinician may be part of a broader group or would have the ability to select some of the cross-cutting measures that are available. Given the wide array of submission options, including QCDRs which have the flexibility to develop additional measures, we believe this scenario should be extremely rare. If we are not able to score the quality performance category, we may reweight their score according to the reweighting policies described in section II.C.7.b.(3)(b) and II.C.7.b.(3)(d) of this proposed rule. We note that we anticipate this will be a rare circumstance given our proposals to allow measures to be submitted and scored via multiple mechanisms within a performance category and to allow facility-based measurement for the quality performance category.

(f) Incentives To Report High Priority Measures

In the CY 2017 Quality Payment Program final rule, we finalized that we would award 2 bonus points for each outcome or patient experience measure and 1 bonus point for each additional high priority measure that is reported in addition to the 1 high priority measure that is already required to be reported under the quality performance category submission criteria, provided the measure has a performance rate greater than zero, and the measure meets the case minimum and data completeness requirements (81 FR 77293). High priority measures were defined as outcome, appropriate use, patient safety, efficiency, patient experience and care coordination measures, as identified in Tables A and E in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77558 and 77686). We also finalized that we will apply measure bonus points for the CMS Web Interface for the Quality Payment Program based on the finalized set of measures reportable through that submission mechanism (81 FR 77293). We note that in addition to the 14 required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure.

We are not proposing any changes to these policies for awarding measure bonus points for reporting high priority measures in this proposed rule.

In the CY 2017 Quality Payment Program final rule, we finalized a cap on high priority measure bonus points at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category for the first 2 years of MIPS (81 FR 77294). Groups that submit via the CMS Web Interface for the Quality Payment Program are also subject to the 10 percent cap on high priority measure bonus points. We are not proposing any changes to the cap on measure bonus points for reporting high priority measures, which is codified at § 414.1380(b)(1)(xiv)(D) [10], in this proposed rule.

(g) Incentives to Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act outlines specific scoring rules to encourage the use of CEHRT under the quality performance category. For more of the statutory background and description of the proposed and finalized policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77294 through 77299).

In the CY 2017 Quality Payment Program final rule at § 414.1380(b)(1)(xiv), we codified that 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria described below (81 FR 77297). We also finalized a policy capping the number of bonus points available for electronic end-to-end reporting at 10 percent of the denominator of the quality performance category percent score, for the first 2 years of the program (81 FR 77297). For example, when the denominator is 60, the number of measure bonus points will be capped at 6 points. We also finalized that the CEHRT bonus would be available to all submission mechanisms except claims submissions. Specifically, MIPS eligible clinicians who report via qualified registries, QCDRs, EHR submission mechanisms, or the CMS Web Interface for the Quality Payment Program, in a manner that meets the end-to-end reporting requirements, may receive 1 bonus point for each reported measure with a cap as described (81 FR 77297).

We are not proposing changes to these policies related to bonus points for using CEHRT for end-to-end reporting in this proposed rule. However, we are seeking comment on the use of health IT in quality measurement and how HHS can encourage the use of certified EHR technology in quality measurement as established in the statute. What other incentives within this category for reporting in an end-to-end manner could be leveraged to incentivize more clinicians to report electronically? What format should these incentives take? For

[10] Redesignated from § 414.1380(b)(1)(xiii)(D).

example, should clinicians who report all of their quality performance category data in an end-to-end manner receive additional bonus points than those who report only partial electronic data? Are there other ways that HHS should incentivize providers to report electronic quality data beyond what is currently employed? We welcome public comment on these questions.

(h) Calculating Total Measure Achievement and Measure Bonus Points

In section II.C.7.a.(2)(i) of this proposed rule, we are proposing a new methodology to reward improvement based on achievement, from 1 year to another, which requires modifying the calculation of the quality performance category percent score. In this section II.C.7.a.(2)(h) of the proposed rule, we are summarizing the policies for calculating the total measure achievement points and total measure bonus points, prior to scoring improvement and the final quality performance category percent score. We note that we will refer to policies finalized in the CY 2017 Quality Payment Program final rule that apply to the quality performance category score, which is referred to as the quality performance category percent score in this proposed rule, in this section. We are also proposing some refinements to address the ability for MIPS eligible clinicians to submit quality data via multiple submission mechanisms.

(i) Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters

In the CY 2017 Quality Payment Program final rule (81 FR 77300), we finalized that if a MIPS eligible clinician elects to report more than the minimum number of measures to meet the MIPS quality performance category criteria, then we will only include the scores for the measures with the highest number of assigned points, once the first outcome measure is scored, or if an outcome measure is not available, once another high priority measure is scored. We are not proposing any changes to the policy to score the measures with the highest number of assigned points in this proposed rule; however, we are proposing refinements to account for measures being submitted across multiple submission mechanisms.

In the CY 2017 Quality Payment Program final rule, we sought comment on whether to score measures submitted across multiple submission mechanisms (81 FR 77275). As described in section II.C.6.a.(1) of this proposed rule, we are proposing that MIPS eligible clinicians be able to submit measures within a performance category via multiple submission mechanisms. In the CY 2017 Quality Payment Program final rule, we also sought comment on what approach we should use to combine the scores for quality measures from multiple submission mechanisms into a single aggregate score for the quality performance category (81 FR 77275). Examples of possible scoring options were a weighted average score on quality measures submitted through two or more different mechanisms or taking the highest scores for any submitted measure regardless of how the measure is submitted. A few comments received in response to the CY 2017 Quality Payment Program final rule did not support developing different weights for different submission methods. One commenter recommended that we take the highest score for any submitted measure, regardless of submission mechanisms, or alternatively, calculate independent scores that would each contribute equally to the final score.

After consideration of the comments we received, we are proposing, beginning with the 2018 MIPS performance period, a method to score quality measures if a MIPS eligible clinician submits measures via more than one of the following submission mechanisms: Claims, qualified registry, EHR or QCDR submission options. We believe that allowing MIPS eligible clinicians to be scored across these data submission mechanisms in the quality performance category will provide additional options for MIPS eligible clinicians to report the measures required to meet the quality performance category criteria, and encourage MIPS eligible clinicians to begin using electronic submission mechanisms, even if they may not have 6 measures to report via a single electronic submission mechanism alone. We note that we also continue to score the CMS-approved survey vendor for CAHPS for MIPS submission options in conjunction with other submission mechanisms (81 FR 77275) as noted in Table 24.

We propose to score measures across multiple mechanisms using the following rules:

- As with the rest of MIPS, we will only score measures within a single identifier. For example, as codified in § 414.1310(e), eligible clinicians and MIPS eligible clinicians within a group aggregate their performance data across the TIN in order for their performance to be assessed as a group. Therefore, measures can only be scored across multiple mechanisms if reported by the same individual MIPS eligible clinician, group, virtual group or APM Entity, as described in Table 24.
- We do not propose to aggregate measure results across different submitters to create a single score for an individual measure (for example, we are not going to aggregate scores from different TINs within a virtual group TIN to create a single virtual group score for the measures; rather, virtual groups must perform that aggregation across TINs prior to data submission to CMS). Virtual groups are treated like other groups and must report all of their measures at the virtual group level, for the measures to be scored. Data completeness and all the other criteria will be evaluated at the virtual group level. Then the same rules apply for selecting which measures are used for scoring. In other words, if a virtual group representative submits some measures via a qualified registry and other measures via EHR, but an individual TIN within the virtual group also submits measures, we will only use the scores from the measures that were submitted at the virtual group level, because the TIN submission does not use the virtual group identifier. This is consistent with our other scoring principles, where, for virtual groups, all quality measures are scored at the virtual group level.
- Separately, as also described in Table 24, because CMS Web Interface and facility-based measurement each have a comprehensive set of measures that meet the proposed MIPS submission requirements, we do not propose to combine CMS Web Interface measures or facility-based measurement with other group submission mechanisms (other than CAHPS for MIPS, which can be submitted in conjunction with the CMS Web Interface). We refer readers to section II.C.7.a.(2)(h)(ii) of this proposed rule for discussion of calculating the total measure achievement and measure bonus points for CMS Web Interface reporters and to section II.C.7.a.(4) of this proposed rule for a description of our proposed policies on facility-based measurement. We list these submission mechanisms in Table 24, to illustrate that CMS Web Interface submissions and facility-based measurement cannot be combined with other submission options, except that the CAHPS for MIPS survey can be combined with CMS Web Interface, as described in section II.C.7.a.(2)(h)(ii) of this proposed rule.

TABLE 24—SCORING ALLOWED ACROSS MULTIPLE MECHANISMS BY SUBMISSION MECHANISM

[Determined by MIPS identifier and submission mechanism]

MIPS identifier and submission mechanisms	When can quality measures be scored across multiple mechanisms?
Individual eligible clinician reporting via claims, EHR, QCDR, and registry submission options.	Can combine claims, EHR, QCDR, and registry.
Group reporting via EHR, QCDR, registry, and the CAHPS for MIPS survey.	Can combine EHR, QCDR, registry, and CAHPS for MIPS survey.
Virtual group reporting via EHR, QCDR, registry, and the CAHPS for MIPS survey.	Can combine EHR, QCDR, registry, and CAHPS for MIPS survey.
Group reporting via CMS Web Interface	Cannot be combined with other submission mechanisms, except for the CAHPS for MIPS survey.
Virtual group reporting via CMS Web Interface	Cannot be combined with other submission mechanisms, except for the CAHPS for MIPS survey.
Individual or group reporting facility-based measures	Cannot be combined with other submission mechanisms.
MIPS APMs reporting Web Interface or other quality measures	MIPS APMs are subject to separate scoring standards and cannot be combined with other submission mechanisms.

• If a MIPS eligible clinician submits the same measure via 2 different submission mechanisms, we will score each mechanism by which the measure is submitted for achievement and take the highest measure achievement points of the 2 mechanisms.

• Measure bonus points for high priority measures would be added for all measures submitted via all the different submission mechanisms available, even if more than 6 measures are submitted, but high priority measure bonus points are only available once for each unique measure (as noted by the measure number) that meets the criteria for earning the bonus point. For example, if a MIPS eligible clinician submits 8 measures—6 process and 2 outcome—and both outcome measures meet the criteria for a high priority bonus (meeting the required data completeness, case minimum, and has a performance rate greater than zero), the outcome measure with the highest measure achievement points would be scored as the required outcome measure and then the measures with the next 5 highest measure achievement points will contribute to the final quality score. This could include the second outcome measure but does not have to. Even if the measure achievement points for the second outcome measure are not part of the quality performance category percent score, measure bonus points would still be available for submitting a second outcome measure and meeting the requirement for the high priority measure bonus points. The rationale for providing measure bonus points for measures that do not contribute measure achievement points to the quality performance category percent score is that it would help create better benchmarks for outcome and other high priority measures by encouraging clinicians to report them even if they may not have high performance on the measure. We also want to encourage MIPS eligible clinicians to submit to us all of their available MIPS data, not only the data that they or their intermediary deem to be their best data. We believe it will be in the best interest of all MIPS eligible clinicians that we determine which measures will result in the clinician receiving the highest MIPS score. If the same measure is submitted through multiple submission mechanisms, we would apply the bonus points only once to the measure. We propose to amend § 414.1380(b)(1)(xiv) (as redesignated from § 414.1380(b)(1)(xiii)) to add paragraph (b)(1)(xiv)(E) that if the same high priority measure is submitted via two or more submission mechanisms, as determined using the measure ID, the measure will receive high priority measure bonus points only once for the measure. The total measure bonus points for high-priority measures would still be capped at 10 percent of the total possible measure achievement points.

• Measure bonus points that are available for the use of end-to-end electronic reporting would be calculated for all submitted measures across all submission mechanisms, including measures that cannot be reliably scored against a benchmark. If the same measure is submitted through multiple submission mechanisms, then we would apply the bonus points only once to the measure. For example, if the same measure is submitted using end-to-end reporting via both a QCDR and EHR reporting mechanism, the measure would only get a measure bonus point one time. We propose to amend § 414.1380(b)(1)(xv) (as redesignated) to add that if the same measure is submitted via two or more submission mechanisms, as determined using the measure ID, the measure will receive measure bonus points only once for the measure. The total measure bonus points for end-to-end electronic reporting would still be capped at 10 percent of the total available measure achievement points.

Although we provide a policy to account for scoring in those circumstances when the same measure is submitted via multiple mechanisms, we anticipate that this will be a rare circumstance and do not encourage clinicians to submit the same measure via multiple mechanisms. Table 25 illustrates how we would assign total measure achievement points and total measure bonus points across multiple submission mechanisms under our proposal. In this example, a MIPS eligible clinician elects to submit quality data via 3 submission mechanisms: 3 Measures via registry, 4 measures via claims, and 5 measures via EHR. The 3 registry measures are also submitted via claims (as noted by the same measure letter in this example). The EHR measures do not overlap with either the registry or claims measures. In this example, we assign measure achievement and bonus points for each measure. If the same measure (as determined by measure ID) is submitted, then we use the highest achievement points for that measure. For the bonus points, we assess which of the outcome measures meets the outcome measure requirement and then we identify any other unique measures that qualify for the high priority bonus. We also identify the unique measures that qualify for end-to-end electronic reporting bonus.

TABLE 25—EXAMPLE OF ASSIGNING TOTAL MEASURE ACHIEVEMENT AND BONUS POINTS FOR AN INDIVIDUAL MIPS ELIGIBLE CLINICIAN THAT SUBMITS MEASURES ACROSS MULTIPLE SUBMISSION MECHANISMS

	Measure achievement points	6 Scored measures	High priority measure bonus points	Incentive for CEHRT measure bonus points
Registry				
Measure A (Outcome)	7.1	7.1 (Outcome measure with highest achievement points).	(required outcome measure does not receive bonus points).	
Measure B	6.2 (points not considered because it is lower than the 8.2 points for the same claims measure).			
Measure C (high priority patient safety measure that meets requirements for additional bonus points).	5.1 (points not considered because it is lower than the 6.0 points for the same claims measure).		1	
Claims				
Measure A (Outcome)	4.1 (points not considered because it is lower than the 7.1 points for the same measure submitted via a registry).		No bonus points because the registry submission of the same measure satisfies requirement for outcome measure.	
Measure B	8.2	8.2		
Measure C (High priority patient safety measure that meets requirements for additional bonus points).	6.0	6.0	No bonus (Bonus applied to the registry measure).	
Measure D (outcome measure <50% of data submitted).	1.0	1.0	(no high priority bonus points because below data completeness).	
EHR (using end-to-end)				*Reporting that meets CEHRT bonus point criteria*
Measure E	5.1	5.1		1
Measure F	5.0	5.0		1
Measure G	4.1			1
Measure H	4.2	4.2		1
Measure I (high priority patient safety measure that is below case minimum).	3.0		(no high priority bonus points because below case minimum).	1
	35.6	1 (below 10% cap[1]).	5 (below 10% cap).	
Quality Performance Category Percent Score Prior to Improvement Scoring.		(35.6 + 1 + 5)/60 = 69.33%		

[1] In this example the cap would be 6 points, which is 10 percent of the total available measure achievement points of 60.

We propose to amend § 414.1380(b)(1)(xii) to add paragraph (A) to state that if a MIPS eligible clinician submits measures via claims, qualified registry, EHR, or QCDR submission options, and submits more than the required number of measures, they are scored on the required measures with the highest assigned measure achievement points. MIPS eligible clinicians that report a measure via more than 1 submission mechanism can be scored on only 1 submission mechanism, which will be the submission mechanism with the highest measure achievement points. Groups that submit via these submission mechanisms may also submit and be scored on CMS-approved survey vendor for CAHPS for MIPS submission mechanisms.

We invite comments on our proposal to calculate the total measure achievement points by using the measures with the 6 highest measure achievement points across multiple submission mechanisms. We invite comments on our proposal that if the same measure is submitted via 2 or more mechanisms, we will only take the one with the highest measure achievement points. We invite comments on our proposal to assign high priority measure bonus points to all measures, with performance greater than zero, that meet case minimums, and that meet data completeness requirements, regardless of submission mechanism and to assign measure

bonus points for each unique measure submitted using end-to-end electronic reporting. We invite comments on our proposal that if the same measure is submitted using 2 different mechanisms, the measure will receive measure bonus points once.

We are not proposing any changes to our policy that if a MIPS eligible clinician does not have any scored measures, then a quality performance category percent score will not be calculated as finalized in the CY 2017 Quality Payment Program final rule at 81 FR 77300. We refer readers to the discussion at 81 FR 77299 through 77300 for more details on that policy. As stated in section II.C.7.a.(2)(e) of this proposed rule, we anticipate that it will be only in rare case that a MIPS eligible clinician does not have any scored measures and a quality performance category percent score cannot be calculated.

(ii) Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters

In the CY 2017 Quality Payment Program final rule, we finalized that CMS Web Interface reporters are required to report 14 measures, 13 individual measures, and a 2-component measure for diabetes (81 FR 77302 through 77305). We note that for the transition year, 3 measures did not have a benchmark in the Shared Savings Program. Therefore, for the transition year, CMS Web Interface reporters are scored on 11 of the total 14 required measures, provided that they report all 14 required measures.

In the CY 2017 Quality Payment Program final rule, we finalized a global floor of 3 points for all CMS Web Interface measures submitted in the transition year, even with measures at zero percent performance rate, provided that these measures have met the data completeness criteria, have a benchmark and meet the case minimum requirements (82 FR 77305). Therefore, measures with performance below the 30th percentile will be assigned a value of 3 points during the transition year to be consistent with the floor established for other measures and because the Shared Savings Program does not publish benchmarks below the 30th percentile (82 FR 77305). We stated that we will reassess scoring for measures below the 30th percentile in future years.

We propose to continue to assign 3 points for measures with performance below the 30th percentile, provided the measure meets data completeness, has a benchmark, and meets the case minimum requirements for the 2018 MIPS performance year; we make this proposal in order to continue to align with the 3-point floor for other measures and because the Shared Savings Program does not publish benchmarks with values below the 30th percentile. We will reassess this policy again next year through rulemaking.

We are not proposing any changes to our previously finalized policy to exclude from scoring CMS Web Interface measures that are submitted but that do not meet the case minimum requirement or that lack a benchmark, or to our policy that measures that are not submitted and measures submitted below the data completeness requirements will receive a zero score (82 FR 77305). However, to further increase alignment with the Shared Savings Program, we propose to also exclude CMS Web Interface measures from scoring if the measure is redesignated from pay for performance to pay for reporting for all Shared Savings Program ACOs, although we will recognize the measure was submitted. While the Shared Savings Program designates measures that are pay for performance in advance of the reporting year, the Shared Savings Program may redesignate a measure as pay for reporting under certain circumstances (see 42 CFR 425.502(a)(5)). Therefore, we propose to amend § 414.1380(b)(1)(viii) to add that CMS Web Interface measures that have a measure benchmark but are redesignated as pay for reporting for all Shared Savings Program ACOs by the Shared Savings Program will not be scored, as long as the data completeness requirement is met.

We invite comment on our proposal to not score CMS Web Interface measures redesignated as pay for reporting by the Shared Savings Program.

We also note that, while we did not state explicitly in the CY 2017 Quality Payment Program final rule, groups that choose to report quality measures via the CMS Web Interface may, in addition to the 14 required measures, also submit the CAHPS for MIPS survey in the quality performance category (81 FR 77094 through 77095; 81 FR 77292). If they do so, they can receive bonus points for submitting this high priority measure and will be scored on it as an additional measure. Therefore, we propose to amend § 414.1380(b)(1)(xii) to add paragraph (B) to state that groups that submit measures via the CMS Web Interface may also submit and be scored on CMS-approved survey vendor for CAHPS for MIPS submission options.

In addition, groups of 16 or more eligible clinicians that meet the case minimum for administrative claims measures will automatically be scored on the all-cause hospital readmission measure and have that measure score included in their quality category performance percent score.

We are not proposing any changes to calculating the total measure achievement points and measure bonus points for CMS Web Interface measures in this proposed rule, although we are proposing to add improvement to the quality performance category percent score for such submissions (as well as other submission mechanisms) in section II.C.7.a.(2)(j) of this proposed rule.

(i) Scoring Improvement for the MIPS Quality Performance Category Percent Score

(i) Calculating Improvement at the Quality Performance Category Level

In the CY 2017 Quality Payment Program final rule, we noted that we consider achievement to mean how a MIPS eligible clinician performs relative to performance standards, and improvement to mean how a MIPS eligible clinician performs compared to the MIPS eligible clinician's own previous performance on measures and activities in the performance category (81 FR 77274). We also solicited public comments in the CY 2017 Quality Payment Program proposed rule on potential ways to incorporate improvement in the scoring methodology. In section II.C.7.a.(1)(b)(i) of this proposed rule, we explain why we believe that the options set forth in the CY 2017 Quality Payment Program proposed rule, including the Hospital VBP Program, the Shared Savings Program, and Medicare Advantage 5-star Ratings Program, were not fully translatable to MIPS. Beginning with the 2018 MIPS performance period, we propose here to score improvement as well as achievement in the quality performance category level when data is sufficient. We believe that scoring improvement at the performance category level, rather than measuring improvement at the measure level, for the quality performance category would allow improvement to be available to the broadest number of MIPS eligible clinicians because we are connecting performance to previous MIPS quality performance as a whole rather than changes in performance for individual measures. Just as we believe it is important for a MIPS eligible clinician to have the flexibility to choose measures that are meaningful to their practice, we want them to be able to adopt new measures without concern

about losing the ability to be measured on improvement. In addition, we are encouraging MIPS eligible clinicians to select more outcome measures and to move away from topped out measures. We do not want to remove the opportunity to score improvement from those who select different measures between performance periods for the quality performance category; therefore, we are proposing to measure improvement at the category level which can be calculated with different measures.

We propose at § 414.1380(b)(1)(xvi)(E) to define an improvement percent score to mean the score that represents improvement for the purposes of calculating the quality performance category percent score. We also propose at § 414.1380(b)(1)(xvi)(C) that an improvement percent score would be assessed at the quality performance category level and included in the calculation of the quality performance category percent score. When we evaluated different improvement scoring options, we saw two general methods for incorporating improvement. One method measures both achievement and improvement and takes the higher of the two scores for each measure that is compared. The Hospital VBP Program incorporates such a methodology. The second method is to calculate an achievement score and then add an improvement score if improvement is measured. The Shared Savings Program utilizes a similar methodology for measuring improvement. For the quality performance category, we are proposing to calculate improvement at the category level and believe adding improvement to an existing achievement percent score would be the most straight-forward and simple way to incorporate improvement. For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the total possible available measure achievement points, without consideration of bonus points or improvement adjustments and is discussed in section II.C.7.a.(2)(i)(iv) of this proposed rule.

Consistent with bonuses available in the quality performance category, we propose at § 414.1380(b)(1)(xvi)(B) that the improvement percent score may not total more than 10 percentage points.

We invite public comments on these proposals.

(ii) Data Sufficiency Standard To Measure Improvement for Quality Performance Category

Section 1848(q)(5)(D)(i) of the Act stipulates that beginning with the second year to which the MIPS applies, if data sufficient to measure improvement is available then we shall measure improvement for the quality performance category. Measuring improvement requires a direct comparison of data from one Quality Payment Program year to another. Starting with the 2020 MIPS payment year, we propose that a MIPS eligible clinician's data would be sufficient to score improvement in the quality performance category if the MIPS eligible clinician had a comparable quality performance category achievement percent score for the MIPS performance period immediately prior to the current MIPS performance period; we explain our proposal to identify how we will identify ''comparable'' quality performance category achievement percent scores below. We believe that this approach would allow improvement to be broadly available to MIPS eligible clinicians and encourage continued participation in the MIPS program. Moreover, this approach would encourage MIPS eligible clinicians to focus on efforts to improve the quality of care delivered. We note that, by measuring improvement based only on the overall quality performance category achievement percent score, some MIPS eligible clinicians and groups may generate an improvement score simply by switching to measures on which they perform more highly, rather than actually improving at the same measures. We will monitor how frequently improvement is due to actual improvement versus potentially perceived improvement by switching measures and will address through future rulemaking, as needed. We also solicit comment on whether we should require some level of year to year consistency when scoring improvement.

We propose that ''comparability'' of quality performance category achievement percent scores would be established by looking first at the submitter of the data. As discussed in more detail in section II.C.7.a.(2)(i)(i) of this proposed rule, we are comparing results at the category, rather than the performance measure level because we believe that the performance category score from 1 year is comparable to the performance category score from the prior year, even if the measures in the performance category have changed from year to year.

We propose to compare results from an identifier when we receive submissions with that same identifier (either TIN/NPI for individual, or TIN for group, APM entity, or virtual group identifier) for two consecutive performance periods. However, if we do not have the same identifier for two consecutive performance periods, we propose a methodology to create a comparable performance category score that can be used for improvement measurement. Just as we do not want to remove the opportunity to earn an improvement score from those who elect new measures between performance periods for the quality performance category, we also do not want to restrict improvement for those MIPS eligible clinicians who elect to participate in MIPS using a different identifier.

There are times when submissions from a particular individual clinician or group of clinicians use different identifiers between 2 years. For example, a group of 20 MIPS eligible clinicians could choose to submit as a group (using their TIN identifier) for the current performance period. If the group also submitted as a group for the previous year's performance period, we would simply compare the group scores associated with the previous performance period to the current performance period (following the methodology explained in section II.C.7.a.(2)(i)(iv) of this proposed rule). However, if the group members had previously elected to submit to MIPS as individual clinicians, we would not have a group score at the TIN level from the previous performance period to which to compare the current performance period.

In circumstances where we do not have the same identifier for two consecutive performance periods, we propose to identify a comparable score for individual submissions or calculate a comparable score for group, virtual group, and APM entity submissions. For individual submissions, if we do not have a quality performance category achievement percent score for the same individual identifier in the immediately prior period, then we propose to apply the hierarchy logic that is described in section II.C.8.a.(2) of this proposed rule to identify the quality performance category achievement score associated with the final score that would be applied to the TIN/NPI for payment purposes. For example, if there is no historical score for the TIN/NPI, but there is a TIN score (because in the previous period the TIN submitted as a group), then we would use the quality performance category achievement

percent score associated with the TIN's prior performance. If the NPI had changed TINs and there was no historical score for the same TIN/NPI, then we would take the highest prior score associated with the NPI.

When we do not have a comparable TIN group, virtual group, or APM Entity score, we propose to calculate a score based on the individual TIN/NPIs in the practice for the current performance period. For example, in a group of 20 clinicians that previously participated in MIPS as individuals, but now want to participate as a group, we would not have a comparable TIN score to use for scoring improvement. We believe however it is still important to provide to the MIPS eligible clinicians the improvement points they have earned. Similarly, in cases where a group of clinicians previously participated in MIPS as individuals, but now participates as a new TIN, or a new virtual group, or a new APM Entity submitting data in the performance period, we would not have a comparable TIN, virtual group, or APM Entity score to use for scoring improvement. Therefore, we propose to calculate a score by taking the average of the individual quality performance category achievement scores for the MIPS eligible clinicians that were in the group for the current performance period. If we have more than one quality performance category achievement percent score for the same individual identifier in the immediately prior period, then we propose to apply the hierarchy logic that is described in section II.C.8.a.(2) of this proposed rule to identify the quality performance category score associated with the final score that would be applied to the TIN/NPI for payment purposes. We would exclude any TIN/NPI's that did not have a final score because they were not eligible for MIPS. We would include quality performance category achievement percent scores of zero in the average.

There are instances where we would not be able to measure improvement due to lack of sufficient data. For example, if the MIPS eligible clinicians did not participate in MIPS in the previous performance period because they were not eligible for MIPS, we could not calculate improvement because we would not have a previous quality performance category achievement percent score.

Table 26 summarizes the different cases when a group or individual would be eligible for improvement scoring under this proposal.

TABLE 26—ELIGIBILITY FOR IMPROVEMENT SCORING EXAMPLES

Scenario	Current MIPS performance period identifier	Prior MIPS performance period identifier (with score greater than zero)	Eligible for improvement scoring	Data comparability
No change in identifier	Individual (TIN A/NPI 1).	Individual (TIN A/NPI 1).	Yes	Current individual score is compared to individual score from prior performance period.
No change in identifier	Group (TIN A)	Group (TIN A)	Yes	Current group score is compared to group score from prior performance period.
Individual is with same group, but selects to submit as an individual whereas previously the group submitted as a group.	Individual (TIN A/NPI 1).	Group (TIN A)	Yes	Current individual score is compared to the group score associated with the TIN/NPI from the prior performance period.
Individual changes practices, but submitted to MIPS previously as an individual.	Individual (TIN B/NPI).	Individual (TIN A/NPI).	Yes	Current individual score is compared to the individual score from the prior performance period.
Individual changes practices and has multiple scores in prior performance period.	Individual (TIN C/NPI).	Group (TIN A/NPI); Individual (TIN B/NPI).	Yes	Current individual score is compared to highest score from the prior performance period.
Group does not have a previous group score from prior performance period.	Group (TIN A)	Individual scores (TIN A/NPI 1, TIN A/NPI 2, TIN A/NPI 3, etc.).	Yes	The current group score is compared to the average of the scores from the prior performance period of individuals who comprise the current group.
Virtual group does not have previous group score from prior performance period.	Virtual Group (Virtual Group Identifier A) (Assume virtual group has 2 TINs with 2 clinicians.).	Individuals (TIN A/NPI 1, TIN A/NPI 2, TIN B/NPI 1, TIN B/NPI 2).	Yes	The current group score is compared to the average of the scores from the prior performance period of individuals who comprise the current group.
Individual does not have a quality performance category achievement score for the prior performance period.	Individual (TIN A/NPI 1).	Individual was not eligible for MIPS and did not voluntarily submit any quality measures to MIPS.	No	The individual quality performance category score is missing for the prior performance period and not eligible for improvement scoring.

We propose at § 414.1380(b)(1)(xvi)(A) to state that improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician or group has a quality performance category achievement percent score for the previous performance period. We also propose at § 414.1380(b)(1)(xvi)(A)(1) that data must be comparable to meet the requirement of data sufficiency,

which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and, therefore, quality performance category achievement percent scores can be compared. We also propose at § 414.1380(b)(1)(xvi)(A)(2) that quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods. We also propose an exception at § 414.1380(b)(1)(xvi)(A)(3) that if the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment. For group, virtual group, and APM entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group. As noted above, these proposals are designed to offer improvement scoring to all MIPS eligible clinicians with sufficient data in the prior MIPS performance period. We invite public comments on our proposals as they relate to data sufficiency for improvement scoring.

We also seek comment on an alternative to this proposal: Whether we should restrict improvement to those who submit quality performance data using the same identifier for two consecutive MIPS performance periods. We believe this option would be simpler to apply, communicate and understand than our proposal is, but this alternative could have the unintended consequence of not allowing improvement scoring for certain MIPS eligible clinicians, groups, virtual groups and APM entities.

(iii) Additional Requirement for Full Participation To Measure Improvement for Quality Performance Category

To receive a quality performance category improvement percent score greater than zero, we are also proposing that MIPS eligible clinicians must fully participate, which we propose in § 414.1380(b)(1)(xvi)(F) to mean compliance with § 414.1330 and § 414.1340, in the current performance year. Compliance with those referenced regulations entails the submission of all required measures, including meeting data completeness, for the quality performance category for the current performance period. For example, for MIPS eligible clinicians submitting via QCDR, full participation would generally mean submitting 6 measures including 1 outcome measure if an outcome measure is available or 1 high priority measure if an outcome measure is not available, and meeting the 50 percent data completeness criteria for each of the 6 measures.

We believe that improvement is most meaningful and valid when we have a full set of quality measures. A comparison of data resulting from full participation of a MIPS eligible clinician from 1 year to another enables a more accurate assessment of improvement because the performance being compared is based on the applicable and available measures for the performance periods and not from changes in participation. While we are not requiring full participation for both performance periods, requiring full participation for the current performance period means that any future improvement scores for a clinician or group would be derived solely from changes in performance and not because the clinician or group submitted more measures. We propose at § 414.1380(b)(1)(xvi)(C)(5) that the quality improvement percent score is zero if the clinician did not fully participate in the quality performance category for the current performance period.

Because we want to award improvement for net increases in performance and not just improved participation in MIPS, we want to measure improvement above a floor for the 2018 MIPS performance period, to account for our transition year policies. We considered that MIPS eligible clinicians who chose the ''test'' option of the ''pick your pace'' approach for the transition year may not have submitted all the required measures and, as a result, may have a relatively low quality performance category achievement score for the 2017 MIPS performance period. Due to the transition year policy to award at least 3 measure achievement points for any submitted measure via claims, EHR, QCDR, qualified registry, and CMS-approved survey vendor for CAHPS for MIPS, and the 3-point floor for the all-cause readmission measure (if the measure applies), a MIPS eligible clinician that submitted some data via these mechanisms on the required number of measures would automatically have a quality performance category achievement score of at least 30 percent because they would receive at least 3 of 10 possible measure achievement points for each required measure. For example, if a solo practitioner submitted 6 measures and received 3 points for each measure, then the solo practitioner would have 18 measure achievement points out of a possible 60 total possible measure achievement points (3 measure achievement points × 6 measures). The quality performance category achievement percent score is 18/60 which equals 30 percent. For groups with 16 or more clinicians that submitted 6 measures and receive 3 measure achievement points for each submitted measure as well as the all-cause hospital readmission measure, then the group would have 21 measure achievement points out of 70 total possible measure achievement points or a quality performance category achievement percent score of 21/70 which equals 30 percent (3 measure achievement points × 7 measures). For the CMS Web Interface submission option, MIPS eligible clinicians that fully participate by submitting and meeting data completeness for all measures, would also be able to achieve a quality performance category achievement percent score of at least 30 percent, as each scored measure would receive 3 measure achievement points out of 10 possible measure achievement points.

Therefore, we propose at § 414.1380(b)(1)(xvi)(C)(4) that if a MIPS eligible clinician has a previous year quality performance category score less than or equal to 30 percent, we would compare 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent. In effect, for the MIPS 2018 performance period, improvement would be measured only if the clinician's 2018 quality performance category achievement percent score for the quality performance category exceeds 30 percent. We believe this approach appropriately recognizes the participation of MIPS eligible clinicians who participated in the transition year and accounts for MIPS eligible clinicians who participated minimally and may otherwise be awarded for an increase in participation rather than an increase in achievement performance.

We invite public comment on these proposals.

(iv) Measuring Improvement Based on Changes in Achievement

To calculate improvement with a focus on quality performance, we are proposing to focus on improvement based on achievement performance and would not consider measure bonus

points in our improvement algorithm. Bonus points may be awarded for reasons not directly related to performance such as the use of end-to-end electronic reporting. We believe that improvement points should be awarded based on improvement related to achievement. Accordingly, we are proposing to use an individual MIPS eligible clinician's or group's total measure achievement points from the prior MIPS performance period without the bonus points the individual MIPS eligible clinician or group may have received, to calculate improvement. Therefore, to measure improvement at the quality performance category level, we will use the quality performance category achievement percent score excluding measure bonus points (and any improvement score) for the applicable years. We propose at § 414.1380(b)(1)(xvi)(D) to call this score, which is based on achievement only, the ''quality performance category achievement percent score'' which is calculated using the following formula:

Quality performance category achievement percent score = total measure achievement points/total available measure achievement points.

Table 27 illustrates how the quality performance category achievement percent score is calculated. For simplicity, we assume the MIPS eligible clinician received 6 measure achievement points for each of the submitted 6 required measures in the current performance period, which equals 36 total measure achievement points. This is compared to the previous performance period when the MIPS eligible clinician received only 5 measure achievement points per measure, for 30 total measure achievement points. The quality performance category achievement percent score is represented in line 2. For improvement, performance in the current 2018 MIPS performance period (60 percent) is compared to the performance category achievement percent score in the 2017 MIPS performance period (50 percent).

TABLE 27—COMPARISON OF QUALITY PERFORMANCE CATEGORY ACHIEVEMENT PERCENT SCORES

	Current MIPS performance period	Previous MIPS performance period
(1) Total Measure Achievement Points	6 measure achievement points × 6 measures = 36 total measure achievement points.	5 measure achievement points × 6 measures = 30 total measure achievement points.
(2) Quality Performance Category Achievement Percent Score (measure achievement points/60 for this example).	36/60 = 60 percent	30/60 = 50 percent.

The current MIPS performance period quality performance category achievement percent score is compared to the previous performance period quality performance category achievement percent score. If the current score is higher, the MIPS eligible clinician may qualify for an improvement percent score to be added into the quality performance category percent score for the current performance year.

We propose to amend the regulatory text at § 414.1380(b)(1)(xvi) to state that improvement scoring is available to MIPS eligible clinicians and groups that demonstrate improvement in performance in the current MIPS performance period compared to the performance in the previous MIPS performance period, based on achievement. Bonus points or improvement percent score adjustments made to the category score in the prior or current performance period are not taken into account when determining whether an improvement has occurred or the size of any improvement percent score.

We invite public comment on our proposal to award improvement based on changes in the quality performance category achievement percent score.

(v) Improvement Scoring Methodology for the Quality Performance Category

We believe the improvement scoring methodology that we are proposing for the quality performance category recognizes the rate of increase in quality performance category scores of MIPS eligible clinicians from one performance period to another performance period so that a higher rate of improvement results in a higher improvement percent score. We believe this is particularly true for those clinicians with lower performance who will be incentivized to begin improving with the opportunity to increase their improvement significantly and achieve a higher improvement percent score.

We propose to award an ''improvement percent score'' based on the following formula:

Improvement percent score = (increase in quality performance category achievement percent score from prior performance period to current performance period/prior year quality performance category achievement percent score) * 10 percent.

Using the example from Table 27, the quality performance category achievement percent score for the current performance period is 60 percent, and the previous performance period achievement percent score is 50 percent. The increase in achievement is 10 percentage points (60 percent—50 percent). Therefore, the improvement percent score is 10 percent (increase in achievement)/50 percent (previous performance period achievement percent score) * 10 percent = 2 percentage points. Another way to explain the logic is a 20 percent rate of improvement for achievement (for example increasing the achievement percent score 10 percentage points which is 20 percent higher than the original 50 percent achievement percent score) is worth a 2 percentage point increase to the quality performance category achievement percent score.

We believe that this improvement scoring methodology provides an easily explained and applied approach that is consistent for all MIPS eligible clinicians. Additionally, it provides additional incentives for MIPS eligible clinicians who are lower performers to improve performance. We believe that providing larger incentives for MIPS eligible clinicians with lower quality performance category scores to improve will not only increase the quality performance category scores but also will have the greatest impact on improving quality for beneficiaries.

We also propose that the improvement percent score cannot be negative (that is, lower than zero percentage points). The improvement percent score would be zero for those who do not have sufficient data or who are not eligible under our proposal for improvement points. For example, as noted in section II.C.7.a.(2)(i)(ii) of this proposed rule, a MIPS eligible clinician would not be eligible for improvement if the clinician was not eligible for MIPS

in the prior performance period and did not have a quality performance category achievement percent score. We are also proposing to cap the size of the improvement award at 10 percentage points, which we believe appropriately rewards improvement and does not outweigh percentage points available through achievement. In effect, 10 percentage points under our proposed formula would represent 100 percent improvement—or doubling of achievement measure points—over the immediately preceding period. For the reasons stated, we anticipate that this amount will encourage participation by individual MIPS eligible clinicians and groups and will provide an appropriate recognition and award for the largest increases in performance improvement.

Table 28 illustrates examples of the proposed improvement percent scoring methodology, which is based on rate of increase in quality performance category achievement percent scores.

TABLE 28—IMPROVEMENT SCORING EXAMPLES BASED ON RATE OF INCREASE IN QUALITY PERFORMANCE CATEGORY ACHIEVEMENT PERCENT SCORES

	Year 1 quality performance category achievement percent score	Year 2 quality performance category achievement percent score	Increase in achievement	Rate of improvement	Improvement percent score
Individual Eligible Clinician #1 (Pick your Pace Test Option).	5% (Will substitute 30% which is the lowest score a clinician can achieve with complete reporting in year 1.).	50	20% Because the year 1 score is below 30%, we measure improvement above 30%.	20%/30%= 0.67	0.67*10% = 6.7% No cap needed.
Individual Eligible Clinician #2.	60%	66	6%	6%/60%= 0.10	0.10*10% = 1.0% No cap needed.
Individual Eligible Clinician #3.	90%	93	3%	3%/90%= 0.033	0.033*10% = 0.3% No cap needed.
Individual Eligible Clinician #4.	30%	70	40%	40%/30%=1.33	1.33*10%=13.3% Apply cap at 10%.

We also considered an alternative to measuring the rate of improvement. The alternative would use band levels to determine the improvement points for MIPS eligible clinicians who qualify for improvement points. Under the band level methodology, a MIPS eligible clinician's improvement points would be determined by an improvement in the quality performance category achievement percent score from 1 year to the next year to determine improvement in the same manner as set forth in the rate of improvement methodology. However, for the band level methodology, an improvement percent score would then be assigned by taking into account a portion (50, 75 or 100 percent) of the improvement in achievement, based on the clinician's performance category achievement percent score for the prior year. Bands would be set for category achievement percent scores, with increases from lower category achievement scores earning a larger portion (percentage) of the improvement points. Under this alternative, simple improvement percentage points for improvement are awarded to MIPS eligible clinicians whose category scores improved across years according to the band level, up to a maximum of 10 percent of the total score.

In Table 29, we illustrate the band levels we considered as part of this alternative proposal. The chart depicts the band level and the improvement points allotted for the increases in improvement scores that fall within the transition year score range.

TABLE 29—BAND LEVEL AND IMPROVEMENT POINTS ALLOTTED FOR DETERMINING IMPROVEMENT PERCENT SCORES

Transition year score range	% Credit for each percent increase in achievement
1–50	100% of increase in achievement.

TABLE 29—BAND LEVEL AND IMPROVEMENT POINTS ALLOTTED FOR DETERMINING IMPROVEMENT PERCENT SCORES—Continued

Transition year score range	% Credit for each percent increase in achievement
51–75	75% of increase in achievement.
75–100	50% of increase in achievement.

Table 30 illustrates examples of the improvement scoring methodology based on band levels. Generally, this methodology would generate a higher improvement percent score for clinicians; however, we believe the policy we proposed would provide a score that better represents true improvement at the performance category level, rather than comparing simple increases in performance category scores.

TABLE 30—EXAMPLES OF IMPROVEMENT SCORING METHODOLOGY BASED ON BAND LEVELS

	Year 1 quality performance category achievement percent score	Year 2 quality performance category achievement percent score	Increase in achievement	Band for improvement adjustment	Improvement percent score (after applying the cap)
Individual Eligible Clinician #1 (Pick your Pace Test Option).	5% (Will substitute 30% which is the lowest score a clinician can achieve with complete reporting in year 1.)	50%	20% Because the year 1 score is below 30%, we measure improvement above 30%.	100%	20%*100%= 20% which is capped at 10%.
Individual Eligible Clinician #2.	60%	66%	6%	75%	6%*75%= 4.5% No cap needed
Individual Eligible Clinician #3.	90%	93%	3%	50%	3%*50%= 1.5% No cap needed

In addition, we considered another alternative that would adopt the improvement scoring methodology of the Shared Savings Program[11] for CMS Web Interface submissions in the quality performance category, but decided to not adopt this approach. Under the Shared Savings Program approach, eligible clinicians and groups that submit through the CMS Web Interface would have been required to submit on the same set of quality measures, and we would have awarded improvement for all eligible clinicians or groups who submitted complete data in the prior year. As Shared Savings Program and Next Generation ACOs report using the CMS Web Interface, using the same improvement score approach would align MIPS with these other programs. We believed it could be beneficial to align improvement between the programs because it would align incentives for those who participate in the Shared Savings Program or ACOs. The Shared Savings Program approach would test each measure for statistically significant improvement or statistically significant decline. We would sum the number of measures with a statistically significant improvement and subtract the number of measures with a statistically significant decline to determine the Net Improvement. We would next divide the Net Improvement in each domain by the number of eligible measures in the domain to calculate the Improvement Score. We would cap the number of possible improvement percentage points at 10.

[11] For additional information on the Shared Savings Program's scoring methodology, we refer readers to the Quality Measurement Methodology and Resources, September 2016, Version 1 and the Medicare Shared Savings Program Quality Measure Benchmarks for the 2016 and 2017 Reporting Years (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP–QM-Benchmarks-2016.pdf*.)

We considered the Shared Savings Program methodology because it would promote alignment with ACOs. We ultimately decided not to adopt this scoring methodology because we believe having a single performance category level approach for all quality performance category scores encourages a uniformity in our approach to improvement scoring and simplifies the scoring rules for MIPS eligible clinicians. It also allows us greater flexibility to compare performance scores across the diverse submission mechanisms, which makes improvement scoring more broadly available to eligible clinicians and groups that elect different ways of participating in MIPS.

We propose to add regulatory text at § 414.1380(b)(1)(xvi)(C)(*3*) to state that an improvement percent score cannot be negative (that is, lower than zero percentage points). We also propose to add regulatory text at § 414.1380(b)(1)(xvi)(C)(*1*) to state that improvement scoring is awarded based on the rate of increase in the quality performance category achievement percent score of individual MIPS eligible clinicians or groups from the current MIPS performance period compared to the score in the year immediately prior to the current MIPS performance period. We also propose to add regulatory text at § 414.1380(b)(1)(xvi)(C)(*2*) to state that an improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score of an individual MIPS eligible clinician or group, which is calculated by comparing the quality performance category achievement percent score the current MIPS performance period to the quality performance category achievement percent score from the MIPS performance period in the year immediately prior to the current MIPS performance period, by the prior year quality performance category achievement percent score, and multiplying by 10 percent.

We invite public comments on our proposal to calculate improvement scoring using a methodology that awards improvement points based on the rate of improvement and, alternatively, on rewarding improvement at the band level or using the Shared Saving Program approach for CMS Web Interface submissions.

(j) Calculating the Quality Performance Category Percent Score Including Improvement

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1380(b)(1)(xv) that the quality performance category score is the sum of all points assigned for the measures required for the quality performance category criteria plus bonus points, divided by the sum of total possible points (81 FR 77300). Using the terminology proposed in section II.C.7.a.(2) of this proposed rule, this formula can be represented as:

Quality performance category percent score = (total measure achievement points + measure bonus points)/ total available measure achievement points.

We propose to incorporate the improvement percent score, which is proposed in section II.C.7.a.(2)(i)(i) of this proposed rule, into the quality performance category percent score. We propose to amend § 414.1380(b)(1)(xv) (redesignated as § 414.1380(b)(1)(xvii)) to add the improvement percent score (as calculated pursuant to proposed paragraph (b)(1)(xvi)(A) through (F)) to the quality performance score. We also propose to amend § 414.1380(b)(1)(xv) (redesignated as § 414.1380(b)(1)(xvii)) to amend the text that states the quality performance category percent score cannot exceed the total possible points for the quality performance category to clarify that the total possible points for

the quality performance category cannot exceed 100 percentage points. Thus, the calculation for the proposed quality performance category percent score including improvement, can be summarized in the following formula:

Quality performance category percent score = ([total measure achievement points + measure bonus points]/ total available measure achievement points) + improvement percent score, not to exceed 100 percent.

This same formula and logic will be applied for both CMS Web Interface and Non-CMS Web Interface reporters.

Table 31 illustrates an example of calculating the quality performance category percent score including improvement for a non-CMS Web Interface reporter. In this example, an individual MIPS eligible clinician received measure achievement points for their 6 required measures, and received 6 measure bonus points. Because this is an individual clinician and the administrative claims based measure is not applicable, the total available measure achievement points for this clinician is 60. The improvement percent score would be calculated based on the proposal in section II.C.7.a.(2)(i) of this proposed rule; Table 31 does not illustrate the underlying calculations for the improvement percent score. To calculate the quality performance category percent score, the total measures achievement points would be summed with the total measure bonus points and then divided by the total available measure achievement points. The improvement percent score would be added to that calculation. The resulting quality performance category percent score cannot exceed 100 percentage points.

TABLE 31—EXAMPLE OF SCORING THE QUALITY PERFORMANCE CATEGORY PERCENT SCORE INCLUDING IMPROVEMENT

	Total measure achievement points	Total measure bonus points	Total available measure achievement points	Calculation prior to improvement	Improvement percent score (%)	Quality performance category percent score
Individual Eligible Clinician	35.6	6	60	(35.6 + 6)/60 = 69.33%.	1.9	69.33% + 1.9% = 71.23%
Individual Eligible Clinician (did not submit in Year 1).	35.6	6	60	(35.6 + 6)/60 = 69.33%.	0	69.33% + 0% = 69.33%
Individual Eligible Clinician (with maximum improvement).	50	6	60	(50 + 6)/60 = 93.33%.	10	93.33% + 10% = 103.33%, which is capped at 100%

We note that the quality performance category percent score is then multiplied by the performance category weight for calculating the final score.

We invite public comment on this overall methodology and formula for calculating the quality performance category percent score.

(3) Scoring the Cost Performance Category

We score the cost performance category using a methodology that is generally consistent with the methodology used for the quality performance category. In the CY 2017 Quality Payment Program final rule (81 FR 77309), we codified at § 414.1380(b)(2) that a MIPS eligible clinician receives 1 to 10 achievement points for each cost measure attributed to the MIPS eligible clinician based on the MIPS eligible clinician's performance compared to the measure benchmark. We establish a single benchmark for each cost measure and base those benchmarks on the performance period (81 FR 77309). Because we base the benchmarks on the performance period, we will not be able to publish the actual numerical benchmarks in advance of the performance period (81 FR 77309). We develop a benchmark for a cost measure only if at least 20 groups (for those MIPS eligible clinicians participating in MIPS as a group practice) or TIN/NPI combinations (for those MIPS eligible clinicians participating in MIPS as an individual) can be attributed the case minimum for the measure (81 FR 77309). If a benchmark is not developed, the cost measure is not scored or included in the performance category (81 FR 77309). For each set of benchmarks, we calculate the decile breaks based on cost measure performance during the performance period and assign 1 to 10 achievement points for each measure based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between (81 FR 77309 through 77310). We also codified at § 414.1380(b)(2)(iii) that a MIPS eligible clinician's cost performance category score is the equally-weighted average of all scored cost measures (81 FR 77311).

In the CY 2017 Quality Payment Program final rule (81 FR 77311), we adopted a final policy to not calculate a cost performance category score if a MIPS eligible clinician or group is not attributed any cost measures because the MIPS eligible clinician or group has not met the case minimum requirements for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group. We inadvertently failed to include this policy in the regulation text and are proposing to codify it under § 414.1380(b)(2)(v).

For more of the statutory background and descriptions of our current policies for the cost performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311).

In section II.C.7.a.(3)(a) of this proposed rule, we propose to add improvement scoring to the cost performance category scoring methodology starting with the 2020 MIPS payment year. We do not propose any changes to the methodology for scoring achievement in the cost performance category for the 2020 MIPS payment year other than the method used for facility-based measurement described in II.C.7.a.(4) of this proposed rule. We are proposing a change in terminology to refer to the ''cost performance category percent score in order to be consistent with the terminology used in the quality performance category. In section II.C.7.a.(2) of this proposed rule, we propose to calculate a ''quality performance category percent score'' which is reflective of performance in the quality performance category based on dividing the sum of total measure achievement points and bonus points by the total available measure achievement points. We propose to revise § 414.1380(b)(2)(iii) to provide that a

MIPS eligible clinician's cost performance category percent score is the sum of the following, not to exceed 100 percent: The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points (which can be expressed as a percentage); and the cost improvement score. This terminology change to refer to the score as a percentage is consistent with the change in section II.C.7.a.(2) for the quality performance category. We discuss our proposals for improvement scoring in the cost performance category in section II.C.7.b.3.(a) of this proposed rule.

(a) Measuring Improvement

(i) Calculating Improvement at the Cost Measure Level

In section II.C.7.a.(1)(b) of this proposed rule, we propose to make available to MIPS eligible clinicians and groups a method of measuring improvement in the quality and cost performance categories. In section II.C.7.a.(2)(i) of this proposed rule, for the quality performance category, we propose to assess improvement on the basis of the score at the performance category level. For the cost performance category, similar to the quality performance category, we propose at § 414.1380(b)(2)(iv) that improvement scoring is available to MIPS eligible clinicians and groups that demonstrate improvement in performance in the current MIPS performance period compared to their performance in the immediately preceding MIPS performance period (for example, demonstrating improvement in the 2018 MIPS performance period over the 2017 MIPS performance period).

In section II.C.7.a.(2)(i) of this proposed rule, we note the various challenges associated with attempting to measure improvement in the quality performance category at the measure level, given the many opportunities available to clinicians to select which measures to report. The cost performance category is not subject to this same issue of measure selection. Cost measures are calculated based on Medicare administrative claims data maintained by CMS, without any additional data input from or reporting by clinicians, and MIPS eligible clinicians are not given the opportunity to select which cost measures apply to them. We believe that there are advantages to measuring cost improvement at the measure level. Principally, MIPS eligible clinicians could see their performance on each cost measure and better understand how practice improvement changes can drive changes for each specific cost measure. Additionally, as discussed in section II.C.7.a.(1)(b)(i) of this proposed rule, other Medicare value-based purchasing programs generally assess performance improvement at the measure level. Therefore, we propose at section § 414.1380(b)(2)(iv)(A) to measure cost improvement at the measure level for the cost performance category.

As described in section II.C.7.a.(1)(b)(ii) of this proposed rule, we believe that we would have data sufficient to measure improvement when we can measure performance in the current performance period compared to the prior performance period. Due to the differences in our proposals for measuring improvement for the quality and cost performance categories, such as measuring improvement at the measure level versus the performance category level, we are proposing a different data sufficiency standard for the cost performance category than for the quality performance category, which is proposed in section II.C.7.a.(2)(i)(ii) of this proposed rule. First, for data sufficient to measure improvement to be available for the cost performance category, the same cost measure(s) would need to be specified for the cost performance category for 2 consecutive performance periods. For the 2020 MIPS payment year, only 2 cost measures, the MSPB measure and the total per capita cost measure, would be eligible for improvement scoring. For a measure to be scored in either performance period, a MIPS eligible clinician would need to have a sufficient number of attributed cases to meet or exceed the case minimum for the measure.

In addition, a clinician would have to report for MIPS using the same identifier (TIN/NPI combination for individuals, TIN for groups, or virtual group identifiers for virtual groups) and be scored on the same measure(s) for 2 consecutive performance periods. We wish to encourage action on the part of clinicians in reviewing and understanding their contribution to patient costs. For example, a clinician who is shown to have lower performance on the MSPB measure could focus on the efficient use of post-acute care and be able to see that improvement reflected in the cost improvement score in future years. This review could highlight opportunities for better stewardship of healthcare costs such as better recognition of unnecessary costs related to common ordering practices. For these reasons, we believe that improvement should be evaluated only when there is a consistent identifier.

Therefore, for the cost performance category, we are proposing at § 414.1380(b)(2)(iv)(B) that we would calculate a cost improvement score only when data sufficient to measure improvement is available. We are proposing that sufficient data would be available when a MIPS eligible clinician participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods (for example, in the 2017 MIPS performance period and the 2018 MIPS performance period). If the cost improvement score cannot be calculated because sufficient data is not available, we are proposing to assign a cost improvement score of zero percentage points. While the total available cost improvement score would be limited at first because only 2 cost measures would be included in both the first and second performance periods of the program (total per capita cost and MSPB), more opportunities for improvement scoring would be available in the future as additional cost measures, including episode-based measures, are added in future rulemaking. MIPS eligible clinicians would be able to review their performance feedback and make improvements compared to the score in their previous feedback.

We invite public comments on these proposals.

(ii) Improvement Scoring Methodology

In section II.C.7.a.(1)(b)(i) of this proposed rule, we discuss a number of different programs and how they measure improvement at the category or measure level as part of their scoring systems. For example, the Hospital Value-Based Purchasing (VBP) Program awards either measure improvement or measure achievement, but not both. In the proposed method for the quality performance category, we compare the overall rate of achievement on all the underlying measures in the quality performance category and measure a rate of overall improvement to calculate an improvement percent score. We then add the improvement percent score after taking into account measure achievement points and measure bonus points as described in proposed § 414.1380(b)(1)(xvii). In reviewing the methodologies that are specified in section II.C.7.a.(1)(b)(i) of this proposed rule that include consideration of improvement at the measure level, we noted that the methodology used in the Shared Savings Program would best reward achievement and improvement

for the cost performance category because this program includes measures for clinicians, the methodology is straightforward, and it only recognizes significant improvement. We propose to quantify improvement in the cost performance category by comparing the number of cost measures with significant improvement in performance and the number of cost measures with significant declines in performance. We propose at § 414.1380(b)(2)(iv)(C) to determine the cost improvement score by subtracting the number of cost measures with significant declines from the number of cost measures with significant improvement, and then dividing the result by the number of cost measures for which the MIPS eligible clinician or group was scored in both performance periods, and then multiplying the result by the maximum cost improvement score. For the 2020 MIPS payment year, improvement scoring would be possible for the total per capita cost measure and the MSPB measure as those 2 measures would be available for 2 consecutive performance periods under our proposals in section II.C.6.d.(3)(a). As in our proposed quality improvement methodology, we propose at § 414.1380(b)(2)(iv)(D) that the cost improvement score could not be lower than zero, and therefore, could only be positive.

We propose to determine whether there was a significant improvement or decline in performance between the 2 performance periods by applying a common standard statistical test, a t-test, as is used in the Shared Savings Program (79 FR 67930 through 67931). The t-test's statistical significance and the t-test's effect size are the 2 primary outputs of the t-test. Statistical significance indicates whether the difference between sample averages is likely to represent an actual difference between populations and the effect size indicates whether that difference is large enough to be practically meaningful. Statistical significance testing in this case assesses how unlikely it is that differences as large as those observed would be due to chance when the performance is actually the same. The test recognizes and appropriately adjusts measures at both high and low levels of performance for statistically significant levels of change. However, as an alternative, we welcome public comments on whether we should consider instead adopting an improvement scoring methodology that measures improvement in the cost performance category the same way we propose to do in the quality performance category; that is, using the rate of improvement and without requiring statistical significance. We refer readers to section II.C.7.a.(2)(i) of this proposed rule for our proposal related to measuring improvement in the quality performance category.

Section 1848(q)(5)(D)(ii) of the Act specifies that the Secretary may assign a higher scoring weight under subparagraph (F) with respect to the achievement of a MIPS eligible clinician than with respect to any improvement of such clinician with respect to a measure, activity, or category described in paragraph (2). We believe that there are many opportunities for clinicians to actively work on improving their performance on cost measures, through more active care management or reductions in certain services. However, we recognize that most clinicians are still learning about their opportunities in cost measurement. We aim to continue to educate clinicians about opportunities in cost measurement and continue to develop opportunities for robust feedback and measures that better recognize the role of clinicians. Since MIPS is still in its beginning years and we understand that clinicians are working hard to understand how we measure costs for purposes of the cost performance category, as well as how we score their performance in all other aspects of the program, we believe improvement scoring in the cost performance category should be limited to avoid creating additional confusion. Based on these considerations, we propose in section II.C.6.d.(2) of this proposed rule to weight the cost performance category at zero percent for the 2020 MIPS payment year/2018 MIPS performance period. With the entire cost performance category proposed to be weighted at zero percent, we believe that the focus of clinicians should be on achievement as opposed to improvement, and therefore we propose at § 414.1380(b)(2)(iv)(E) that although improvement would be measured according to the method described above, the maximum cost improvement score for the 2020 MIPS payment year would be zero percentage points. Section 1848(q)(5)(D)(ii) of the Act provides discretion for the Secretary to assign a higher scoring weight under subparagraph (F), which refers to section 1848(q)(5)(F) of the Act, with respect to achievement than with respect to improvement. Section 1848(q)(5)(F) of the Act provides if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician, the Secretary shall assign different scoring weights (including a weight of zero) for measures, activities, and/or performance categories. When read together, we interpret sections 1848(q)(5)(D)(ii) and 1848(q)(5)(F) of the Act to provide discretion to the Secretary to assign a scoring weight of zero for improvement on the measures specified for the cost performance category. Under the improvement scoring methodology we have proposed, we believe a maximum cost improvement score of zero would be effectively the same as a scoring weight of zero. As a result of our proposal, the cost improvement score would not contribute to the cost performance category percent score calculated for the 2020 MIPS payment year. In other words, we would calculate a cost improvement score, but the cost improvement score would not contribute any points to the cost performance category percent score for the 2020 MIPS payment year.

In section II.C.6.d.(2) of this proposed rule, we consider an alternative to make no changes to the previously finalized weight of 10 percent for the cost performance category for the 2020 MIPS payment year. If we finalize this alternative, we believe that improvement should be given weight towards the cost performance category percent score, but it should still be limited. Therefore, we propose that if we maintain a weight of 10 percent for the cost performance category for the 2020 MIPS payment year, the maximum cost improvement score available in the cost performance category would be 1 percentage point out of 100 percentage points available for the cost performance category percent score. If a clinician were measured on only one measure consistently from one performance period to the next and met the requirements for improvement, the clinician would receive one improvement percentage point in the cost performance category percent score. If a clinician were measured on 2 measures consistently, improved significantly on one, and did not show significant improvement on the other (as measured by the t-test method described above), the clinician would receive 0.5 improvement percentage points.

We invite comments on these proposals as well as alternative ways to measure changes in statistical significance for the cost measure.

(b) Calculating the Cost Performance Category Percent Score With Achievement and Improvement

In section II.C.7.a.(1)(b) of this proposed rule, we evaluated different improvement scoring options used in other CMS programs. In those programs, we saw 2 general methods for

incorporating improvement. One method measures both achievement and improvement and takes the higher of the 2 scores for each measure that is compared. The Hospital VBP Program incorporates such a methodology. The second method is to calculate an achievement score and then add an improvement score if improvement is measured. The Shared Savings Program utilizes a similar methodology for measuring improvement. For the cost performance category, we are proposing to evaluate improvement at the measure level, unlike the quality performance category where we are proposing to evaluate improvement at the performance category level. For both the quality performance category and the cost performance category, we are proposing to add improvement to an existing category percent score. We believe this is the most straight-forward and simple way to incorporate improvement. It is also consistent with other Medicare programs that reward improvement.

As noted in section II.7.b.(3) of this proposed rule, we have proposed a change in terminology to express the cost performance category percent score as a percentage. We propose to revise § 414.1380(b)(2)(iii) to provide that a MIPS eligible clinician's cost performance category percent score is the sum of the following, not to exceed 100 percent: The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points (which can be expressed as a percentage); and the cost improvement score. With these two proposed changes, the formula would be (Cost Achievement Points/Available Cost Achievement Points) + (Cost Improvement Score) = (Cost Performance Category Percent Score).

We invite public comments on these proposals.

In Table 32, we provide an example of cost performance category percent scores along with the determination of improvement or decline. For illustrative purposes, we are using the alternative proposal of a maximum cost improvement score of 1. This example is for group reporting where the group is measured on both the total per capita cost measure and the MSPB measure for 2 consecutive performance periods.

TABLE 32—EXAMPLE OF ASSESSING ACHIEVEMENT AND IMPROVEMENT IN THE COST PERFORMANCE CATEGORY

Measure	Measure achievement points earned by the group	Total possible measure achievement points	Significant improvement from prior performance period	Significant decline from prior performance period
Total per Capita Cost Measure	8.2	10	Yes	No
MSPB Measure	6.4	10	No	No

In this example, there are 20 total possible measure achievement points and 14.6 measure achievement points earned by the group, and the group improved on one measure but not the other, with both measures being scored in each performance period. The cost improvement score would be determined as follows: ((1 measure with significant improvement − zero measures with significant decline)/2 measures) * 1 percentage point = 0.5 percentage points. Under the proposed revised formula, the cost performance category percent score would be (14.6/20) + 0.5% = 73.5%.

As discussed in section II.C.7.b.(2) of this proposed rule, in determining the MIPS final score, the cost performance category percent score is multiplied by the cost performance category weight. For the 2020 MIPS payment year, if we finalize the cost performance category weight of zero percent, then the cost performance category percent score will not contribute to the final score.

(4) Facility-Based Measures Scoring Option for the 2020 MIPS Payment Year for the Quality and Cost Performance Categories

(a) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. In the MIPS and APMs RFI (80 FR 59108), we sought comment on how we could best use this authority. We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77127) for a summary of these comments.

As noted in the CY 2017 Quality Payment Program proposed rule (81 FR 28192), we considered an option for facility-based MIPS eligible clinicians to elect to use their institution's performance rates as a proxy for the MIPS eligible clinician's quality score. However, we did not propose an option for the transition year of MIPS because there were several operational considerations that we believed needed to be addressed before this option could be implemented. We requested comments on the following issues: (1) Whether we should attribute a facility's performance to a MIPS eligible clinician for purposes of the quality and cost performance categories and under what conditions such attribution would be appropriate and representative of the MIPS eligible clinician's performance; (2) possible criteria for attributing a facility's performance to a MIPS eligible clinician for purposes of the quality and cost performance categories; (3) the specific measures and settings for which we can use the facility's quality and cost data as a proxy for the MIPS eligible clinician's quality and cost performance categories; and (4) if attribution should be automatic or if an individual MIPS eligible clinician or group should elect for it to be done and choose the facilities through a registration process.

As noted in the CY 2017 Quality Payment Program final rule (81 FR 77127 through 77130), the majority of the comments we received supported attributing a facility's performance to a MIPS eligible clinician for purposes of the quality and cost performance categories. Some commenters opposed using a facility's quality and cost performance as a proxy for MIPS eligible clinicians. Many of these commenters expressed the view that facility scores do not represent the individual MIPS eligible clinician's performance. In addition, we received suggestions on how we should attribute a facility's performance to a MIPS eligible clinician, as well as comments suggesting that attribution should be voluntary and that the facility's measures should be relevant to the MIPS eligible clinician. A full discussion of the comments we received

and our responses can be found in the CY 2017 Quality Payment Program final rule (81 FR 77127 through 77130).

In addition, we have received ongoing feedback from various stakeholder associations and individuals regarding facility-based measurement for MIPS eligible clinicians, which included: Support for MIPS eligible clinicians being able to choose to be assessed in this manner; several groups' preference that value-based purchasing and quality reporting program measure data be used for facility-based scoring; support for a ''hybrid'' approach where MIPS eligible clinicians could select both clinician-based measures and facility-based measures for purposes of MIPS scoring; and a suggested 2-year pilot program before expanding facility-based scoring more broadly with an emphasis on no negative impact on those who are measured in this fashion. We took this feedback, as well as the comments discussed in the CY 2017 Quality Payment Program final rule, into consideration when developing proposals for the application of facility-based measures.

(b) Facility-Based Measurement

We believe that facility-based measurement is intended to reduce reporting burden on facility-based MIPS eligible clinicians by leveraging existing quality data sources and value-based purchasing experiences and aligning incentives between facilities and the MIPS eligible clinicians who provide services there. In addition, we believe that facility-based MIPS eligible clinicians contribute substantively to their respective facilities' performance on facility-based measures of quality and cost, and that their performance may be better reflected by their facilities' performance on such measures.

Medicare operates both pay-for-reporting programs and pay-for-performance programs. Pay-for-reporting programs incentivize the act of reporting data on quality and/or other measures and activities, typically by applying a downward payment adjustment to facilities or clinicians, as applicable, that fail to submit data as required by the Secretary. This type of program does not adjust payments based on performance. In contrast, pay-for-performance programs, such as VBP programs, score facilities or clinicians, as applicable, on their performance on specified quality and/or other measures and activities and adjust payments based on that performance. Pay-for-performance programs, such as VBP programs, are more analogous to MIPS given its focus on performance and not just reporting. For this reason, we believe that facility-based measurement under MIPS should be based on pay-for-performance programs rather than pay-for-reporting programs.

Many Medicare payment systems include a pay-for-performance program, such as the Hospital VBP Program, the Skilled Nursing Facility VBP Program (SNF VBP), the End Stage Renal Disease Quality Incentive Program (ESRD QIP), and the Home Health Value-Based Purchasing Program (HHVBP). We believe that clinicians play a role in contributing to quality performance in all of these programs. However, we believe that a larger and more diverse group of clinicians contributes to quality in the inpatient hospital setting than in other settings in which we might begin to implement this measurement option. In addition, the inpatient hospital setting has a mature value-based purchasing program, first established to adjust payment for hospitals in FY 2013 (76 FR 26489). Therefore, we believe it is appropriate to implement this scoring option in a limited fashion in the first year of incorporating additional facility-based measures under MIPS by focusing on inpatient hospital measures that are used for certain pay-for-performance programs as facility-based measures.

The inpatient hospital setting includes three distinct pay-for-performance programs: The Hospital VBP Program, the Hospital Readmissions Reduction Program (HRRP), and the Hospital-Acquired Condition Reduction Program (HACRP). We believe that the Hospital VBP Program is most analogous to the MIPS program at this time because the Hospital VBP Program compares facilities on a series of different measures that intend to capture the breadth of care provided in a facility. In contrast, the HACRP and HRRP each focus on a single type of outcome for patients treated in a hospital (safety and readmissions, respectively), though we note that these outcomes are critically important to health care improvement. The payment adjustments associated with those 2 programs are intended to provide negative adjustments for poor performance but do not similarly reward high performance. In contrast, the Hospital VBP Program compares performance among hospitals and rewards high performers and provides negative adjustments to poor performers.

We also considered program timing when determining what Hospital VBP Program year to use for facility-based measurement for the 2020 MIPS payment year. Quality measurement for the FY 2019 Hospital VBP Program's performance period will be concluded by December 31, 2017 (we refer readers to the finalized FY 2019 performance periods in the FY 2017 Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System Final Rule, 81 FR 57002), and the Hospital VBP Program scoring reports (referred to as the Percentage Payment Summary Reports) will be provided to participating hospitals not later than 60 days prior to the beginning of FY 2019, pursuant to the Hospital VBP Program's statutory requirement at section 1886(o)(8) of the Act. We further note that hospitals must meet case and measure minimums during the performance period to receive a Total Performance Score under that Program. We discuss eligibility for facility-based measurement in section II.C.7.b.(4)(c) of this proposed rule, and we note that the determination of the applicable hospital will be made on the basis of a period that overlaps with the applicable Hospital VBP Program performance period. Although Hospital VBP Program measures have different measurement periods, the FY 2019 measures all overlap from January to June in 2017, which also overlaps with our first 12-month period to determine MIPS eligibility.

We believe that MIPS eligible clinicians electing the facility-based measurement option under MIPS should be able to consider as much information as possible when making that decision, including how their attributed hospital performed in the Hospital VBP Program because an individual clinician is a part of the clinical team in the hospital, rather than the sole clinician responsible for care as tracked by quality measures. Therefore, we concluded that we should be as transparent as possible with MIPS eligible clinicians about their potential facility-based scores before they begin data submission for the MIPS performance period since this policy option is intended to minimize reporting burdens on clinicians that are already participating in quality improvement efforts through other CMS programs. We expect that MIPS eligible clinicians that would consider facility-based scoring would generally be aware of their hospital's performance on its quality measures, but believe that providing this information directly to clinicians ensures that such clinicians are fully aware of the implications of their scoring elections under MIPS. However, we note that this policy could conceivably place non-facility-based MIPS eligible clinicians at a competitive

disadvantage since they would not have any means by which to ascertain their MIPS measure scores in advance. We view that compromise as a necessity to maximize transparency, and we request comment on whether this notification in advance of the conclusion of the MIPS performance period is appropriate, or if we should consider notifying facility-based clinicians later in the MIPS performance period or even after its conclusion. Notification after the MIPS performance period would prevent facility-based clinicians from being able to compare their expected MIPS performance category scores under the facility-based measurement option with their expected scores under the options available to all MIPS eligible clinicians and pick the higher of the two. Since higher performance category scores may result in a higher final score and a higher MIPS payment adjustment, there is a substantial incentive for a clinician to undertake this comparison, a comparison unavailable to non-facility-based peers.

The performance periods proposed in section II.C.5. of this proposed rule for the 2020 MIPS payment year occur in 2018, with data submission for most mechanisms starting in January 2019. To provide potential facility-based scores to clinicians by the time the data submission period for the 2018 MIPS performance period begins assuming that timeframe is operationally feasible), we believe that the FY 2019 program year of the Hospital VBP Program, as well as the corresponding performance periods, is the most appropriate program year to use for purposes of facility-based measurement under the quality and cost performance categories for the 2020 MIPS payment year. However, we note also that Hospital VBP performance periods can run for periods as long as 36 months, and for some FY 2019 Hospital VBP Program measures, the performance period begins in 2014. We request comment on whether this lengthy performance period duration should override our desire to include all Hospital VBP Program measures as discussed further below. We propose at § 414.1380(e)(6)(iii) that the performance period for facility-based measurement is the performance period for the measures for the measures adopted under the value-based purchasing program of the facility of the year specified.

We considered whether we should include the entire set of Hospital VBP Program measures for purposes of facility-based measurement under MIPS or attempt to differentiate those which may be more influenced by clinicians' contribution to quality performance than others. However, we believe that clinicians have a broad and important role as part of the healthcare team at a hospital and that attempting to differentiate certain measures undermines the team-based approach of facility-based measurement. We propose at § 414.1380(e)(6)(i) that the quality and cost measures are those adopted under the value-based purchasing program of the facility program for the year specified.

Therefore, we propose for the 2020 MIPS payment year to include all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures. Under this proposal, we consider the FY 2019 Hospital VBP Program measures to meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act, and we propose at § 414.1380(e)(1)(i) that facility-based measures available for the 2018 MIPS performance period are the measures adopted for the FY 2019 Hospital VBP Program year authorized by section 1886(o) of the Act and codified in our regulations at §§ 412.160 through 412.167. Measures in the FY 2019 Hospital VBP Program have different performance periods as noted in Table 33.

We request comments on these proposals. We also request comments on what other programs, if any, we should consider including for purposes of facility-based measurement under MIPS in future program years.

(c) Facility-Based Measurement Applicability

(i) General

The percentage of professional time a clinician spends working in a hospital varies considerably. Some clinicians may provide services in the hospital regularly, but also treat patients extensively in an outpatient office or another environment. Other clinicians may practice exclusively within a hospital. Recognizing the various levels of presence of different clinicians within a hospital environment, we seek to limit the potential applicability of facility-based measurement to those MIPS eligible clinicians with a significant presence in the hospital.

In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240), we adopted a definition of ''hospital-based MIPS eligible clinician'' under § 414.1305 for purposes of the advancing care information performance category. Section 414.1305 defines a hospital-based MIPS eligible clinician as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting, based on claims for a period prior to the performance period as specified by CMS. We considered whether we should simply use this definition to determine eligibility for facility-based measurement under MIPS. However, we are concerned that this definition could include many clinicians that have limited or no presence in the inpatient hospital setting. We have noted that hospital-based clinicians may not have control over important aspects of the certified EHR technology that is available in the hospital setting (81 FR 77238). In that regard, there is little difference between outpatient and inpatient hospital settings. But we are proposing to determine a MIPS eligible clinician's quality performance category score and cost performance category score based on a hospital's Hospital VBP performance, which is based on inpatient services. Section 1848(q)(2)(C)(ii) of the Act limits our ability to incorporate measures used for hospital outpatient departments. Our proposal at section II.C.6.f.(7)(a)(i) of this proposed rule to expand the definition of a hospital-based MIPS eligible clinician for the advancing care information performance category to include clinicians who practice primarily in off-campus outpatient hospitals could include clinicians that practice many miles away from the hospital in practices which are owned by the hospital, but do not substantially contribute to the hospital's Hospital VBP Program performance. As we discuss further in this section, the measures used in the Hospital VBP Program are focused on care provided in the inpatient setting. We do not believe it is appropriate for a MIPS eligible clinician to use a hospital's Hospital VBP Program performance for MIPS scoring if they did not provide services in that setting.

Therefore, we believe establishing a different definition for purposes of facility-based measurement is necessary to implement this option. We also note that, since we are seeking comments above on other programs to consider including for purposes of facility-based measurement in future years, we believe establishing a separate definition that could be expanded as needed for this purpose is appropriate. We propose at § 414.1380(e)(2) that a MIPS eligible clinician is eligible for facility-based

measurement under MIPS if they are determined facility-based as an individual. We propose at § 414.1380(e)(2)(i) that a MIPS eligible clinician is considered facility-based as an individual if the MIPS eligible clinician furnishes 75 percent or more of their covered professional services (as defined in section 1848(k)(3)(A) of the Act) in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, as identified by POS code 21, or an emergency room, as identified by POS code 23, based on claims for a period prior to the performance period as specified by CMS. We understand that the services of some clinicians who practice solely in the hospital are billed using place of service codes such as code 22, reflecting an on-campus outpatient hospital for patients who are in observation status. Because there are limits on the length of time a Medicare patient may be seen under observation status, we believe that these clinicians would still furnish 75 percent or more of their covered professional services using POS code 21, but seek comment on whether a lower or higher threshold of inpatient services would be appropriate. We do not propose to include POS code 22 in determining whether a clinician is facility-based because many clinicians who bill for services using this POS code may work on a hospital campus but in a capacity that has little to do with the inpatient care in the hospital. In contrast, we believe those who provide services in the emergency room or the inpatient hospital clearly contribute to patient care that is captured as part of the Hospital VBP Program because many patients who are admitted are admitted through the emergency room. We seek comments on whether POS 22 should be included in determining if a clinician is facility-based and how we might distinguish those clinicians who contribute to inpatient care from those who do not. We note that the inclusion of any POS code in our definition is pending technical feasibility to link a clinician to a facility under the method described in section II.C.7.b.(4)(d) of this proposed rule.

We note that this more limited definition would mean that a clinician who is determined to be facility-based likely would also be determined to be hospital-based for purposes of the advancing care information performance category, because this proposed definition of facility-based is narrower than the hospital-based definition established for that purpose. Clinicians would be determined to be facility-based through an evaluation of covered professional services between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period with a 30-day claims run out. For example, for the 2020 MIPS payment year, where we have adopted a performance period of CY 2018 for the quality and cost performance categories, we would use the data available at the end of October 2017 to determine whether a MIPS eligible clinician is considered facility-based by our definition. At that time, those data would include Medicare claims with dates of service between September 1, 2016 and August 31, 2017. In the event that it is not operationally feasible to use claims from this exact time period, we would use a 12-month period as close as practicable to September 1 of the calendar year 2 years preceding the performance period and August 31 of the calendar year preceding the performance period. This determination would allow clinicians to be made aware of their eligibility for facility-based measurement near the beginning of the MIPS performance period. We believe that this definition allows us to identify MIPS eligible clinicians who are significant contributors to facilities' care for Medicare beneficiaries and other patients for purposes of facility-based measurement.

We also recognize that in addition to the variation in the percentage of time a clinician is present in the hospital, there is also great variability in the types of services that clinicians perform. Some may be responsible for overall management of patients throughout their stay, others may perform a procedure, and others may serve a role in supporting diagnostics. We considered whether certain clinicians should be identified as eligible for this facility-based measurement option based on characteristics in addition to their percentage of covered professional services furnished in the inpatient hospital or emergency room setting, such as by requiring a certain specialty such as hospital medicine or by limiting eligibility to those who served in patient-facing roles. However, we believe that all MIPS eligible clinicians with a significant presence in the facility play a role in the overall performance of a facility, and therefore, are not proposing at this time to further limit this option based on characteristics other than the percentage of covered professional services furnished in an inpatient hospital or emergency room setting. Additionally, we believe that allowing facility-based MIPS eligible clinicians the most flexibility possible, while still being able to accurately measure the value of care those clinicians provide, as we continue implementation of the Quality Payment Program is paramount in ensuring that clinicians understand the program and its effects on the care they provide.

We request comments on this proposal.

(ii) Facility-Based Measurement Group Participation

We are also proposing at § 414.1380(e)(2) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined facility-based as part of a group. We are proposing at § 414.1380(e)(2)(ii) that a facility-based group is a group in which 75 percent or more of the MIPS eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals as defined in § 414.1380(e)(2)(i). We also considered an alternative proposal in which a facility-based group would be a group where the TIN overall furnishes 75 percent or more of its covered professional services (as defined in section 1848(k)(3)(A) of the Act) in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, as identified by POS code 21, or the emergency room, as identified by POS code 23, based on claims for a period prior to the performance period as specified by CMS. Groups would be determined to be facility-based through an evaluation of covered professional services between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period with a 30 day claims run out period (or if not operationally feasible to use claims from this exact time period, a 12-month period as close as practicable to September 1 of the calendar year 2 years preceding the performance period and August 31 of the calendar year preceding the performance period).

We request comments on our proposal and alternative proposal.

(d) Facility Attribution for Facility-Based Measurement

Many MIPS eligible clinicians provide services at more than one hospital, so we must develop a method to identify which hospital's scores should be associated with that MIPS eligible clinician under this facility-based measurement option. We considered

whether a clinician should be required to identify for us the hospital with which they were affiliated, but felt that such a requirement would add unnecessary administrative burden in a process that we believe was intended to reduce burden. We also considered whether we could combine scores from multiple hospitals, but believe that such a combination would reduce the alignment between a single hospital and a clinician or group and could be confusing for participants. We believe we must establish a reasonable threshold for a MIPS eligible clinician's participation in clinical care at a given facility to allow that MIPS eligible clinician to be scored using that facility's measures. We do not believe it to be appropriate to allow MIPS eligible clinicians to claim credit for facilities' measures if the MIPS eligible clinician does not participate meaningfully in the care provided at a given facility.

Therefore, we propose at § 414.1380(e)(5) that MIPS eligible clinicians who elect facility-based measurement would receive scores derived from the value-based purchasing score (using the methodology described in section II.B.7.b.4 of this proposed rule) for the facility at which they provided services for the most Medicare beneficiaries during the period of September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period with a 30 day claims run out. This mirrors our period of determining if a clinician is eligible for facility-based measurement and also overlaps with parts of the performance period for the applicable Hospital VBP program measures. For the first year, the value-based purchasing score for the facility is the FY 2019 Hospital VBP Program's Total Performance Score. In cases in which there was an equal number of Medicare beneficiaries treated at more than one facility, we propose to use the value-based purchasing score from the facility with the highest score.

(e) Election of Facility-Based Measurement

Stakeholders have expressed a strong preference that facility-based measurement be a voluntary process, and we agree with this preference considering our general goal in making MIPS as flexible as possible. Therefore, we propose at § 414.1380(e)(3) that individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility's performance must elect to do so. We propose that those clinicians or groups who are eligible for and wish to elect facility-based measurement would be required to submit their election during the data submission period as determined at § 414.1325(f) through the attestation submission mechanism established for the improvement activities and advancing care information performance categories. If technically feasible, we would let the MIPS eligible clinician know that they were eligible for facility-based measurement prior to the submission period, so that MIPS eligible clinicians would be informed if this option is available to them.

We also considered an alternative approach of not requiring an election process but instead automatically applying facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement, if technically feasible. Under this approach, we would calculate a MIPS eligible clinician's facility-based measurement score based on the hospital's (as identified using the process described in section II.C.6.b. of this proposed rule) performance using the methodology described in section II.C.7.a.2.b. of this proposed rule, and automatically use that facility-based measurement score for the quality and cost performance category scores if the facility-based measurement score is higher than the quality and cost performance category scores as determined based on data submitted by the MIPS eligible clinician through any available reporting mechanism. This facility-based measurement score would be calculated even if an individual MIPS eligible clinician or group did not submit any data for the quality performance category. This option would reduce burden for MIPS eligible clinicians by not requiring them to elect facility-based measurement, but is contrary to stakeholders' request for a voluntary policy. Additionally, under this option, our considerations about Hospital VBP Program timing would be less applicable. That is, we explained our rationale for specifying the FY 2019 Hospital VBP Program above, in part to ensure that MIPS eligible clinicians are informed about their potential facility-based scores prior to the conclusion of the MIPS performance period. However, under an automatic process, we could consider automatically using other Hospital VBP Program years' scores. For example, we could apply FY 2020 Hospital VBP Program scores instead of FY 2019. We intend in general to align Hospital VBP and MIPS performance periods when feasible, and the timing considerations we described above led us to conclude that FY 2019 was the most appropriate Hospital VBP Program year for the first year of the facility-based measurement option under MIPS, and selecting other years would result in further divergence between the MIPS performance period and the Hospital VBP Program's performance periods. We are also concerned that a method that does not require active selection may result in MIPS eligible clinicians being scored on measures at a facility and being unaware that such scoring is taking place. We are also concerned that such a method could provide an advantage to those facility-based clinicians who do not submit quality measures in comparison to those who work in other environments. We also note that this option may not be technically feasible for us to implement for the 2018 MIPS performance period.

We invite comments on this proposal and alternate proposal.

(e) Facility-Based Measures

For the FY 2019 program year, the Hospital VBP Program has adopted 13 quality and efficiency measures. The Hospital VBP Program currently includes 4 domains: Person and community engagement, clinical care, safety, and efficiency and cost reduction. These domains align with many MIPS high priority measures (outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in the quality performance category and the efficiency and cost reduction domain closely aligns with our cost performance category. We believe this set of measures covering 4 domains and composed primarily of measures that would be considered high priority under the MIPS quality performance category capture a broad picture of hospital-based care. For example, the HCAHPS survey under the Hospital VBP Program is a patient experience measure, which would make it a high-priority measure under MIPS. Additionally, the Hospital VBP Program has adopted several measures of clinical outcomes in the form of 30-day mortality measures, and clinical outcomes are a high-priority topic for MIPS. The Hospital VBP Program includes several measures in a Safety domain, which meets our definition of patient safety measures as high-priority. Therefore, we propose that facility-based individual MIPS eligible clinicians or groups that are attributed to a hospital would be scored on all the measures on which the hospital is scored for the Hospital VBP Program via the Hospital VBP Program's Total

Performance Score (TPS) scoring methodology.

The Hospital VBP Program's FY 2019 measures, and their associated performance periods, have been reproduced in Table 33 (see 81 FR 56985 and 57002).

TABLE 33—FY 2019 HOSPITAL VBP PROGRAM MEASURES

Short name	Domain/measure name	NQF No.	Performance period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)	CY 2017
Clinical Care Domain			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230	July 1, 2014—June 30, 2017
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229	July 1, 2014—June 30, 2017
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	July 1, 2014—June 30, 2017
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550	January 1, 2015—June 30, 2017
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	CY 2017
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139	CY 2017
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	CY 2017
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716	CY 2017
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717	CY 2017
PSI–90*	Patient Safety for Selected Indicators (Composite Measure)	0531	July 1, 2015—June 30 2017
PC–01	Elective Delivery	0469	CY 2017
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB).	2158	CY 2017

* PSI–90 has been proposed in the FY 2018 IPPS/LTCH PPS proposed rule for removal beginning with the FY 2019 program year.

We note that the Patient Safety Composite Measure (PSI–90) was proposed for removal beginning with the FY 2019 measure set in the FY 2018 IPPS/LTCH proposed rule (82 FR 19970) due to issues with calculating the measure score. If the proposal to remove that measure from the hospital measure set is finalized, we would remove the measure from the list of those adopted for facility-based measurement in the MIPS program.

We propose at § 414.1380(e)(4) that there are no data submission requirements for the facility-based measures used to assess performance in the quality and cost performance categories, other than electing the option through attestation as proposed in section II.C.7.a.(4)(e). We also refer readers to section II.C.7. of this proposed rule for further details on how we will incorporate scoring for facility-based measurements into MIPS.

(f) Scoring Facility-Based Measurement

(i) Hospital VBP Program Scoring

As we discuss above in subsection (b), we believe that the Hospital VBP Program represents the most appropriate value-based purchasing program with which to begin implementation of the facility-based measurement option under MIPS.

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. These value-based incentive payments are funded through a reduction to participating hospitals' base-operating DRG payment amounts, with the amount of the reduction specified by statute. For the FY 2019 program year, that reduction will be equal to 2 percent. Participating hospitals then receive value-based incentive payments depending on their performance on measures adopted

under the Program. For more detail on the statutory background and history of the Hospital VBP Program's implementation, we refer readers to 81 FR 56979.

As noted previously, the FY 2019 Hospital VBP Program will score participating hospitals on 13 measures covering 4 domains of care, although as discussed in the FY 2018 IPPS/LTCH proposed rule (82 FR 19970), we have proposed to remove the PSI 90 Patient Safety Composite measure from the FY 2019 measure set. For each of the measures, performance standards are established for the applicable fiscal year that include levels of achievement and improvement. For the FY 2019 program year, the achievement threshold and benchmark are calculated using baseline period data with respect to that fiscal year, with the achievement threshold for each of these measures being the median of hospital performance on the measure during the baseline period and the benchmark for each of these measures being the arithmetic mean of the top decile of hospital performance during the baseline period. The achievement threshold and benchmark for the MSPB measure are calculated using the same methodology, except that we use performance period data instead of baseline period data in our calculations. We then calculate hospital performance on each measure during the performance period for which they have sufficient data and calculate a measure score based on that performance as compared with the performance standards that apply to the measure. For achievement scoring, those hospitals that perform below (or above in the case of measures for which a lower rate is better) the level of the achievement threshold are not awarded any achievement points. Those that perform between the level of the achievement threshold and the benchmark are awarded points based on the relative performance of the hospital, according to formulas specified by the Hospital VBP Program (see the Hospital Inpatient VBP Program final rule, 76 FR 26518 through 26519). Those hospitals whose performance meets or exceeds the benchmark are awarded 10 achievement points for the measure. Hospitals are also provided the opportunity to receive improvement points based on their improvement between the baseline period for the measure and the performance period. A hospital is awarded between 0 and 10 points for achievement and 0 and 9 points for improvement, and is awarded the higher of the 2 scores for each individual measure. There are no floors established for scoring and no bonus points are available in this scoring system.

Points awarded for measures within each domain are summed to reach the unweighted domain score. We note for the person and community engagement domain only, the domain score consists of a base score and a consistency score. The base score is based on the greater of improvement or achievement points for each of the 8 HCAHPS survey dimensions. Consistency points are awarded based on a hospital's lowest HCAHPS dimension score during the performance period relative to national hospital scores on that dimension during the baseline period. The domain scores are then weighted according to domain weights specified each Program year, then summed to reach the Total Performance Score, which is converted to a value-based incentive payment percentage that is used to adjust payments to each hospital for inpatient services furnished during the applicable program year. For the FY 2019 program year, all 4 domains will be weighted equally. We refer readers to 81 FR 57005 and 81 FR 79857 through 79858 for additional information on the Hospital VBP Program's performance standards, as well as the QualityNet Web site for certain technical updates to the performance standards.

(ii) Applying Hospital VBP Program Scoring to the MIPS Quality and Cost Performance Categories

We considered several methods to incorporate facility-based measures into scoring for the 2020 MIPS payment year, including selecting hospitals' measure scores, domain scores, and the Hospital VBP Program Total Performance Scores to form the basis for the cost and quality performance category scores for individual MIPS eligible clinicians and groups that are eligible to participate in facility-based measurement. Although each of these approaches may have merit, we have proposed the option that we believe provides the fairest comparison between performance in the 2 programs and will best allow us to expand the opportunity to other programs in the future.

Unlike MIPS, the Hospital VBP Program does not have performance categories. There are instead four domains of measures. We considered whether we should try to identify certain domains or measures that were more closely aligned with those identified in the quality performance category or the cost performance category. We also considered whether we should limit the application of facility-based measurement to the quality performance category and calculate the cost performance category score as we do for other clinicians. However, we believe that value-based purchasing programs are generally constructed to assess an overall picture of the care provided by the facility, taking into account both the costs and the quality of care provided. Given our focus on alignment between quality and cost, we also do not believe it is appropriate to measure quality on one unit (a hospital) and cost on another (such as an individual clinician or TIN). Therefore, we propose at § 414.1380(e) that facility-based scoring is available for the quality and cost performance categories and that the facility-based measurement scoring standard is the MIPS scoring methodology applicable for those who meet facility-based eligibility requirements and who elect facility-based measurement.

(iii) Benchmarking Facility-Based Measures

Measures in the MIPS quality performance category are benchmarked to historical performance on the basis of performance during the 12-month calendar year that is 2 years prior to the performance period for the MIPS payment year. If a historical benchmark cannot be established, a benchmark is calculated during the performance period. In the cost performance category, benchmarks are established during the performance period because changes in payment policies year to year can make it challenging to compare performance on cost measure year to year. Although we propose a different performance period for MIPS eligible clinicians in facility-based measurement, the baseline period used for creating MIPS benchmarks is generally consistent with this approach. We note that the Hospital VBP Program uses measures for the same fiscal year even if those measures do not have the same performance period length, but the baseline period closes well before the performance period. The MSPB is benchmarked in a manner that is similar to measures in the MIPS cost performance category. The MSPB only uses a historical baseline period for improvement scoring and bases its achievement threshold and benchmark solely on the performance period (81 FR 57002). We propose at § 414.1380(e)(6)(ii) that the benchmarks for facility-based measurement are those that are adopted under the value-based purchasing program of the facility for the year specified.

(iv) Assigning MIPS Performance Category Scores Based on Hospital VBP Performance

Performance measurement in the Hospital VBP Program and MIPS is quite different in part due to the design and the maturity of the programs. As noted above, the Hospital VBP Program only assigns achievement points to a hospital for its performance on a measure if the hospital's performance during the performance period meets or exceeds the median of hospital performance on that measure during the applicable baseline period, whereas MIPS assigns achievement points to all measures that meet the required data completeness and case minimums. In addition, the Hospital VBP Program has removed many process measures and topped out measures since its first program year (FY 2013), while both process and topped out measures are available in MIPS. With respect to the FY 2017 program year, for example, the median Total Performance Score for a hospital in Hospital VBP was 33.88 out of 100 possible points. If we were to simply assign the Hospital VBP Total Performance Score for a hospital to a clinician, the performance of those MIPS eligible clinicians electing facility-based measurement would likely be lower than most who participated in the MIPS program, particularly in the quality performance category.

We believe that we should recognize relative performance in the facility programs that reflects their different designs. Therefore, we propose at § 414.1380(e)(6)(iv) that the quality performance category score for facility-based measurement is reached by determining the percentile performance of the facility determined in the value-based purchasing program for the specified year as described under § 414.1380(e)(5) and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those clinicians who are not scored using facility-based measurement. We also propose at § 414.1380(e)(6)(v) that the cost performance category score for facility-based measurement is established by determining the percentile performance of the facility determined in the value-based purchasing program for the specified year as described in § 414.1380(e)(5) and awarding the number of points associated with that same percentile performance in the MIPS cost performance category score for those clinicians who are not scored using facility-based measurement. For example, if the median Hospital VBP Program Total Performance Score was 35 out of 100 possible points and the median quality performance category percent score in MIPS was 75 percent and the median cost performance category score was 50 percent, then a clinician or group that is evaluated based on a hospital that received an Hospital VBP Program Total Performance Score of 35 points would receive a score of 75 percent for the quality performance category and 50 percent for the cost performance category. The percentile distribution for both the Hospital VBP Program and MIPS would be based on the distribution during the applicable performance periods for each of the programs and not on a previous benchmark year.

We believe this proposal offers a fairer comparison of the performance among participants in MIPS and the Hospital VBP Program compared to other options we considered and provides an objective means to normalize differences in measured performance between the programs. In addition, we believe this method will make it simpler to apply the concept of facility-based measurement to additional programs in the future.

We welcome public comments on this proposal.

(v) Scoring Improvement for Facility-Based Measurement

The Hospital VBP Program includes a methodology for recognizing improvement on individual measures which is then incorporated into the total performance score for each participating hospital. A hospital's performance on a measure is compared to a national benchmark as well as its own performance from a corresponding baseline period.

In this proposed rule, we have proposed to consider improvement in the quality and cost performance categories. In section II.C.7.a.(2)(i) of this proposed rule, we propose to measure improvement in the quality performance category based on improved achievement for the performance category percent score and award improvement even if, under certain circumstances, a clinician moves from one identifier to another from 1 year to the next. For those who may be measured under facility-based measurement, improvement is already captured in the scoring method used by the Hospital VBP Program, so we do not believe it is appropriate to separately measure improvement using the proposed MIPS methodology. Although the improvement methodology is not identical, a hospital that demonstrated improvement in the individual measures would in turn receive a higher score through the Hospital VBP Program methodology, so that improvement is reflected in the underlying Hospital VBP Program measurement. In addition, improvement is already captured in the distribution of MIPS performance scores that is used to translate Hospital VBP Total Performance Score into a MIPS quality performance category score. Therefore, we are not proposing any additional improvement scoring for facility-based measurement for either the quality or cost performance category.

Because we intend to allow clinicians the flexibility to elect facility-based measurement on an annual basis, some clinicians may be measured through facility-based measurement in 1 year and through another MIPS method in the next. Because the first MIPS performance period in which a clinician could switch from facility-based measurement to another MIPS method would be in 2019, we seek comment on how to assess improvement for those that switch from facility-based scoring to another MIPS method. We request comment on whether it is appropriate to include measurement of improvement in the MIPS quality performance category for facility-based measured clinicians and groups given that the Hospital VBP Program already takes improvement into account in its scoring methodology.

In section II.C.7.a.(3)(a) of this proposed rule, we discuss our proposal to measure improvement in the cost performance category at the measure level. We propose that clinicians under facility-based measurement would not be eligible for a cost improvement score in the cost performance category. As in the quality performance category, we believe that a clinician participating in facility-based measurement in subsequent years would already have improvement recognized as part of the Hospital VBP Program methodology and should therefore not be given additional credit. In addition, because we propose to limit measurement of improvement to those MIPS eligible clinicians that participate in MIPS using the same identifier and are scored on the same cost measure(s) in 2 consecutive performance periods, those MIPS eligible clinicians who elect facility-based measurement would not be eligible for a cost improvement score in the cost performance category under our proposed methodology because they would not be scored on the same cost measure(s) for 2 consecutive performance periods.

We invite comments on these proposals.

(vi) Bonus Points for Facility-Based Measurement

MIPS eligible clinicians that report on quality measures are eligible for bonus points for the reporting of additional outcome and high priority measures beyond the one that is required. 2 bonus points are awarded for each additional outcome or patient experience measure, and one bonus point is awarded for each additional other high priority measure. These bonus points are intended to encourage the use of measures that are more impactful on patients and better reflect the overall goals of the MIPS program. Many of the measures in the Hospital VBP Program meet the criteria that we have adopted for high-priority measures. We support measurement that takes clinicians' focus away from clinical process measures; however, our proposed scoring method described above is based on a percentile distribution of scores within the quality and cost performance categories that already accounts for bonus points. For this reason, we are not proposing to calculate additional high priority bonus points for facility-based measurement.

We note that clinicians have an additional opportunity to receive bonus points in the quality performance category score for using end-to-end electronic submission of quality measures. The Hospital VBP Program does not capture whether or not measures are reported using end-to-end electronic reporting. In addition, our proposed facility-based scoring method described above is based on a percentile distribution of scores within the quality and cost performance categories that already accounts for bonus points. For this reason, we are not proposing to calculate additional end-to-end electronic reporting bonus points for facility-based measurement.

We welcome public comments on our approach.

(vii) Special Rules for Facility-Based Measurement

Some hospitals do not receive a Total Performance Score in a given year in the Hospital VBP Program, whether due to insufficient quality measure data, failure to meet requirements under the Hospital Inpatient Quality Reporting Program, or other reasons. In these cases, we would be unable to calculate a facility-based score based on the hospital's performance, and facility-based clinicians would be required to participate in MIPS via another method. Most hospitals which do not receive a Total Performance Score in the Hospital VBP Program are routinely excluded, such as hospitals in Maryland. In such cases, facility-based clinicians would know well in advance that the hospital would not receive a Total Performance Score, and that they would need to participate in MIPS through another method. However, we are concerned that some facility-based clinicians may provide services in hospitals which they expect will receive a Total Performance Score but do not due to various rare circumstances such as natural disasters. In section II.C.7.b.(3)(c) of this proposed rule, we propose a process for requesting a reweighting assessment for the quality, cost and improvement activities performance categories due to extreme and uncontrollable circumstances, such as natural disasters. We propose that MIPS eligible clinicians who are facility-based and affected by extreme and uncontrollable circumstances, such as natural disasters, may apply for reweighting.

In addition, we note that hospitals may submit correction requests to their Total Performance Scores calculated under the Hospital VBP Program, and may also appeal the calculations of their Total Performance Scores, subject to Hospital VBP Program requirements established in prior rulemaking. We intend to use the final Hospital VBP Total Performance Score for the facility-based measurement option under MIPS. In the event that a hospital obtains a successful correction or appeal of its Total Performance Score, we would update MIPS eligible clinicians' quality and cost performance category scores accordingly, as long as the update could be made prior to the application of the MIPS payment adjustment for the relevant MIPS payment year. We welcome public comments on whether a different deadline should be considered.

Additionally, although we wish to tie the hospital and clinician performance as closely together as possible for purposes of the facility-based scoring policy, we do not wish to disadvantage those clinicians and groups that select this measurement method. In section II.C.7.a.(2) of this proposed rule, we propose to retain a policy equivalent to the 3-point floor for all measures with complete data in the quality performance category scored against a benchmark in the 2020 MIPS payment year. However, the Hospital VBP Program does not have a corresponding scoring floor. Therefore, we propose to adopt a floor on the Hospital VBP Program Total Performance Score for purposes of facility-based measurement under MIPS so that any score in the quality performance category, once translated into the percentile distribution described above, that would result in a score of below 30 percent would be reset to a score of 30 percent in the quality performance category. We believe that this adjustment is important to maintain consistency with our other policies. There is no similar floor established for measures in the cost performance category under MIPS, so we do not propose any floor for the cost performance category for facility-based measurement.

Some MIPS eligible clinicians who select facility-based measurement could have sufficient numbers of attributed patients to meet the case minimums for the cost measures established under MIPS. Although there is no additional data reporting for cost measures, we believe that, to facilitate the relationship between cost and quality measures, they should be evaluated covering the same population as opposed to comparing a hospital population and a population attributed to an individual clinician or group. In addition, we believe that including additional cost measures in the cost performance category score for MIPS eligible clinicians who elect facility-based measurement would reduce the alignment of incentives between the hospital and the clinician. Thus, we are proposing at § 414.1380(e)(6)(v)(A) that MIPS eligible clinicians who elect facility-based measurement would not be scored on other cost measures specified for the cost performance category, even if they meet the case minimum for a cost measure.

If a clinician or a group elects facility-based measurement but also submits quality data through another MIPS mechanism, we propose to use the higher of the two scores for the quality performance category and base the score of the cost performance category on the same method (that is, if the facility-based quality performance category score is higher, facility-based measurement is used for quality and cost). Since this policy may result in a higher final score, it may provide facility-based clinicians with a substantial incentive to elect facility-based measurement, whether or not the clinician believes such measures are the most accurate or useful measures of that clinician's performance. Therefore, this policy may create an unfair advantage for facility-based clinicians over non-facility-based clinicians, since non-facility-based clinicians would not have the opportunity to use the higher of two scores. Therefore, we seek comment on whether this proposal to use the higher score is the best approach to score the performance of facility-based clinicians

in comparison to their non-facility-based peers.

(5) Scoring the Improvement Activities Performance Category

Section 1848(q)(5)(C) of the Act specifies scoring rules for the improvement activities performance category. For more of the statutory background and description of the proposed and finalized policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77311 through 77319). We have also codified certain requirements for the improvement activities performance category at § 414.1380(b)(3). Based on these criteria, we finalized at § 414.1380(b)(3) in the CY 2017 Quality Payment Program final rule the scoring methodology for this category, which assigns points based on certified patient-centered medical home participation or comparable specialty practice participation, APM participation, and the improvement activities reported by the MIPS eligible clinician (81 FR 77312). A MIPS eligible clinician's performance will be evaluated by comparing the reported improvement activities to the highest possible score (40 points). We are not proposing any changes to the scoring of the improvement activities performance category in this proposed rule.

(a) Assigning Points to Reported Improvement Activities

We will assign points for each reported improvement activity within 2 categories: Medium-weighted and high-weighted activities. Each medium-weighted activity is worth 10 points toward the total category score of 40 points, and each high-weighted activity is worth 20 points toward the total category score of 40 points. These points are doubled for small practices, practices in rural areas, or practices located in geographic HPSAs, and non-patient facing MIPS eligible clinicians. We refer readers to § 414.1380(b)(3) and the CY 2017 Quality Payment Program final rule (81 FR 78312) for further detail on improvement activities scoring.

Activities will be weighted as high based on the extent to which they align with activities that support the certified patient-centered medical home, since that is consistent with the standard under section 1848(q)(5)(C)(i) of the Act for achieving the highest potential score for the improvement activities performance category, as well as with our priorities for transforming clinical practice (81 FR 77311). Additionally, activities that require performance of multiple actions, such as participation in the Transforming Clinical Practice Initiative (TCPI), participation in a MIPS eligible clinician's state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) are justifiably weighted as high (81 FR 77311 through 77312).

We refer readers to Table 26 of the CY 2017 Quality Payment Program final rule for a summary of the previously finalized improvement activities that are weighted as high (81 FR 77312 through 77313), and we refer readers to Table H of the same final rule, for a list of all the previously finalized improvement activities, both medium- and high-weighted (81 FR 77817 through 77831). Please refer to Table F and Table G in the appendices of this proposed rule for proposed additions and changes to the Improvement Activities Inventory for the 2020 MIPS payment year and future years. Activities included in these proposed tables would apply for the 2020 MIPS payment year and future years unless further modified via notice and comment rulemaking. Consistent with our unified scoring system principles, we finalized in the CY 2017 Quality Payment Program final rule that MIPS eligible clinicians will know in advance how many potential points they could receive for each improvement activity (81 FR 77311 through 77319).

(b) Improvement Activities Performance Category Highest Potential Score

At § 414.1380(b)(3), we finalized that we will require a total of 40 points to receive the highest score for the improvement activities performance category (81 FR 77315). For more of the statutory background and description of the proposed and finalized policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77314 through 77315).

For small practices, practices in rural areas and geographic HPSA practices and non-patient facing MIPS eligible clinicians, the weight for any activity selected is doubled so that these practices and eligible clinicians only need to select one high- or two medium-weighted activities to achieve the highest score of 40 points (81 FR 77312).

In accordance with section 1848(q)(5)(C)(ii) of the Act, we codified at § 414.1380(b)(3)(ix) that individual MIPS eligible clinicians or groups who are participating in an APM (as defined in section 1833(z)(3)(C) of the Act) for a performance period will automatically earn at least one half of the highest potential score for the improvement activities performance category for the performance period. In addition, MIPS eligible clinicians that are participating in MIPS APMs will be assigned an improvement activity score, which may be higher than one half of the highest potential score. This assignment is based on the extent to which the requirements of the specific model meet the list of activities in the Improvement Activities Inventory. For a further description of improvement activities and the APM scoring standard for MIPS, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77246). For all other individual MIPS eligible clinicians or groups, we refer readers to the scoring requirements for individual MIPS eligible clinicians and groups in the CY 2017 Quality Payment Program final rule (81 FR 77270). An individual MIPS eligible clinician or group is not required to perform activities in each improvement activities subcategory or participate in an APM to achieve the highest potential score in accordance with section 1848(q)(5)(C)(iii) of the Act (81 FR 77178).

In the CY 2017 Quality Payment Program final rule, we also finalized that individual MIPS eligible clinicians and groups that successfully participate and submit data to fulfill the requirements for the CMS Study on Improvement Activities and Measurement will receive the highest score for the improvement activities performance category (81 FR 77315). We refer readers to section II.C.6.e.(7) of this proposed rule for further detail on this study.

(c) Points for Certified Patient-Centered Medical Home or Comparable Specialty Practice

Section 1848(q)(5)(C)(i) of the Act specifies that a MIPS eligible clinician who is in a practice that is certified as a patient-centered medical home or comparable specialty practice for a performance period, as determined by the Secretary, must be given the highest potential score for the improvement activities performance category for the performance period. Accordingly, at § 414.1380(b)(3)(iv), we specify that a MIPS eligible clinician who is in a practice that is certified as a patient-centered medical home, including a Medicaid Medical Home, Medical Home Model, or comparable specialty practice, will receive the highest potential score for the improvement activities performance category (81 FR 77196 through 77180).

We are not proposing any changes to the scoring of the patient-centered medical home or comparable specialty

practice; although we are proposing a change to how groups qualify for this activity. We refer readers to section II.C.6.e. of this proposed rule for a discussion of the requirements for certified patient-centered medical home practices or comparable specialty practices.

(d) Calculating the Improvement Activities Performance Category Score

In the CY 2017 Quality Payment Program final rule (81 FR 77318), we finalized that individual MIPS eligible clinicians and groups must earn a total of 40 points to receive the highest score for the improvement activities performance category. To determine the improvement activities performance category score, we sum the points for all of a MIPS eligible clinician's reported activities and divide by the improvement activities performance category highest potential score of 40. A perfect score will be 40 points divided by 40 possible points, which equals 100 percent. If MIPS eligible clinicians have more than 40 improvement activities points we will cap the resulting improvement activities performance category score at 100 percent.

Section 1848(q)(2)(B)(iii) of the Act requires the Secretary to give consideration to the circumstances of small practices and practices located in rural areas and in geographic HPSAs (as designated under section 332(a)(1)(A) of the PHS Act) in defining activities. Section 1848(q)(2)(C)(iv) of the Act also requires the Secretary to give consideration to non-patient facing MIPS eligible clinicians. Further, section 1848(q)(5)(F) of the Act allows the Secretary to assign different scoring weights for measures, activities, and performance categories, if there are not sufficient measures and activities applicable and available to each type of eligible clinician.

Accordingly, we finalized that the following scoring applies to MIPS eligible clinicians who are a non-patient facing MIPS eligible clinician, a small practice (consisting of 15 or fewer professionals), a practice located in a rural area, or practice in a geographic HPSA or any combination thereof:

- Reporting of one medium-weighted activity will result in 20 points or one-half of the highest score.
- Reporting of two medium-weighted activities will result in 40 points or the highest score.
- Reporting of one high-weighted activity will result in 40 points or the highest score.

The following scoring applies to MIPS eligible clinicians who are not a non-patient facing clinician, a small practice, a practice located in a rural area, or a practice in a geographic HPSA:

- Reporting of one medium-weighted activity will result in 10 points which is one-fourth of the highest score.
- Reporting of two medium-weighted activities will result in 20 points which is one-half of the highest score.
- Reporting of three medium-weighted activities will result in 30 points which is three-fourths of the highest score.
- Reporting of four medium-weighted activities will result in 40 points which is the highest score.
- Reporting of one high-weighted activity will result in 20 points which is one-half of the highest score.
- Reporting of two high-weighted activities will result in 40 points which is the highest score.
- Reporting of a combination of medium-weighted and high-weighted activities where the total number of points achieved are calculated based on the number of activities selected and the weighting assigned to that activity (number of medium-weighted activities selected $\times$ 10 points + number of high-weighted activities selected $\times$ 20 points) (81 FR 78318).

We also finalized in the CY 2017 Quality Payment Program final rule that certain activities in the improvement activities performance category will also qualify for a bonus under the advancing care information performance category (81 FR 78318). This bonus will be calculated under the advancing care information performance category and not under the improvement activities performance category. We refer readers to section II.C.6.f.5.(d) of this proposed rule for further details. For more information about our finalized improvement activities scoring policies and for several sample scoring charts, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 78319). Finally, in that same final rule, we codified at § 414.1380(b)(3)(ix) that MIPS eligible clinicians participating in APMs that are not certified patient-centered medical homes will automatically earn a minimum score of one-half of the highest potential score for the performance category, as required by section 1848(q)(5)(C)(ii) of the Act. For any other MIPS eligible clinician who does not report at least one activity, including a MIPS eligible clinician who does not identify to us that they are participating in a certified patient-centered medical home or comparable specialty practice, we will calculate a score of zero points (81 FR 77319).

(e) Self-Identification Policy for MIPS Eligible Clinicians

We also noted in the CY 2017 Quality Payment Program final rule (81 FR 77319), that individual MIPS eligible clinicians or groups participating in APMs would not be required to self-identify as participating in an APM, but that all MIPS eligible clinicians would be required to self-identify if they were part of a certified patient-centered medical home or comparable specialty practice, a non-patient facing MIPS eligible clinician, a small practice, a practice located in a rural area, or a practice in a geographic HPSA or any combination thereof, and that we would validate these self-identifications as appropriate. However, beginning with the 2018 MIPS performance period, we are proposing to no longer require these self-identifications for a non-patient facing MIPS eligible clinician, a small practice, a practice located in a rural area, or a practice in a geographic HPSA or any combination thereof because it is technically feasible for us to identify these MIPS eligible clinicians during attestation to the performance of improvement activities following the performance period. We define these MIPS eligible clinicians in the CY 2017 Quality Payment Program final rule (81 FR 77540), and they are discussed in this proposed rule in section II.C.1. of this proposed rule. However, MIPS eligible clinicians that are part of a certified patient-centered medical home or comparable specialty practice are still required to self-identify for the 2018 MIPS performance period, and we will validate these self-identifications as appropriate. We refer readers to section II.C.6.e.3.(c) of this proposed rule for the criteria for recognition as a certified patient-centered medical home or comparable specialty practice.

(6) Scoring the Advancing Care Information Performance Category

We refer readers to section II.C.6.f. of this proposed rule with comment period, where we discuss scoring the advancing care information performance category.

b. Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329) and § 414.1380. In this proposed rule, we propose to add a complex patient scoring bonus and add a small practice bonus to the final score. In addition, we review the final score calculation for the

2020 MIPS payment year and propose refinements to the reweighting policies.

(1) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, that section provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under the MIPS. In doing this, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 and, as appropriate, other information, including information collected before completion of such studies and recommendations. We refer readers to our discussion of risk factors for the transition year of MIPS (81 FR 77320 through 77321).

In this section, we summarize our efforts related to social risk and the relevant studies conducted under section 2(d) of the IMPACT Act of 2014. We also propose some short-term adjustments to address patient complexity.

(a) Considerations for Social Risk

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted the first of several Reports to Congress on a study it was required to conduct under section 2(d) of the IMPACT Act of 2014. The first study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[12] The report also included considerations for strategies to account for social risk factors in these programs. A second report due October 2019 will expand on these initial analyses, supplemented with non-Medicare datasets to measure social risk factors. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for accounting for social risk factors, including stratified public reporting.[13]

As noted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56974), the NQF has undertaken a 2-year trial period in which certain new measures and measures undergoing maintenance, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these and any future reports, and await the results of the NQF trial on risk adjustment for quality measures, we are continuing in this proposed rule to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in the MIPS, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors in the MIPS. Examples of methods include: Adjustment of MIPS eligible clinician scores (for example, stratifying the scores of MIPS eligible clinicians based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to MIPS eligible clinicians; public reporting of stratified measure results; risk adjustment of a particular measure as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for clinicians caring for patients with social risk factors or incentivizing clinicians to achieve health equity). We are seeking comments on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in MIPS, if any.

In addition, we are seeking public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to the following: Dual eligibility/low-income subsidy; race and ethnicity; and geographic area of residence. We are seeking comment on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in MIPS. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by

[12] Office of the Assistant Secretary for Planning and Evaluation. 2016. 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.*

[13] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

providers and suppliers is assessed fairly in CMS programs.

(b) Complex Patient Bonus

While we work with stakeholders on these issues as we have described, we are proposing, under the authority within section 1848(q)(1)(G) of the Act, which allows us to assess and implement appropriate adjustments to payment adjustments, MIPS final scores, scores for performance categories, or scores for measures or activities under MIPS, to implement a short-term strategy for the Quality Payment Program to address the impact patient complexity may have on final scores. The overall goal when considering a bonus for complex patients is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We used the term ''patient complexity'' to take into account a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, as well as social risk factors. We believe that as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources in order to achieve health outcomes that are similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program. Our proposal is intended to address any discrepancy, without masking performance. Because this bonus is intended to be a short-term strategy, we are proposing the bonus only for the 2018 MIPS performance period (2020 MIPS payment year) and will assess on an annual basis whether to continue the bonus and how the bonus should be structured.

When considering approaches for a complex patient bonus, we reviewed evidence to identify how indicators of patient complexity have an impact on performance under MIPS as well as availability of data to implement the bonus. Specifically, we identified two potential indicators for complexity: Medical complexity as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients with dual eligible status. We identified these indicators because they are common indicators of patient complexity in the Medicare program and the data is readily available. As discussed below, both of these indicators have been used in Medicare programs to account for risk and both data elements are already publicly available for individual NPIs in the Medicare Physician and Other Supplier Public Use File (referred to as the Physician and Other Supplier PUF) (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicare-provider-charge-data/physician-and-other-supplier.html*). While we recognize that these indicators are interrelated (as dual eligible status is one of the factors included in calculation of HCC risk scores), we intend for the sake of simplicity to implement one of these indicators for the 2020 MIPS payment year.

We believe that average HCC risk scores are a valid proxy for medical complexity that have been used by other CMS programs. The HCC model was developed by CMS as a risk-adjustment model that uses hierarchical condition categories to assign risk scores to Medicare beneficiaries. Those scores estimate how Medicare beneficiaries' FFS spending will compare to the overall average for the entire Medicare population. According to the Physician and Other Supplier PUF methodological overview, published in January of 2017,[14] the average risk score is set at 1.08; beneficiaries with scores greater than that are expected to have above-average spending, and vice versa. Risk scores are based on a beneficiary's age and sex; whether the beneficiary is eligible for Medicaid, first qualified for Medicare on the basis of disability, or lives in an institution (usually a nursing home); and the beneficiary's diagnoses from the previous year. The HCC model was designed for risk adjustment on larger populations, such as the enrollees in an MA plan, and generates more accurate results when used to compare groups of beneficiaries rather than individuals. For more information on the HCC risk score, see: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html*.

HCC risk scores have been used in the VM to apply an additional upward payment adjustment of +1.0x for clinicians whose attributed patient population has an average risk score that is in the top 25 percent of all beneficiary risk scores (77 FR 69325 through 69326). CMS proposes and announces changes to the HCC risk adjustment model as part of the announcement of payment policies for Medicare Advantage plans under section 1853 of the Act; the proposals and announcements are posted at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*.

A mean HCC risk score for a MIPS eligible clinician can be calculated by averaging the HCC risk scores for the beneficiaries cared for by the clinician. In considering options for a complex patient bonus, we explored the use of average HCC risk scores while recognizing that ''complexity'' is one of several drivers of that metric. We believe that using the HCC risk score as a proxy for patient complexity is a helpful starting point, and will explore methods for further distinguishing complexity from other reasons a clinician could receive a high average HCC risk score.

In addition to medical complexity, patient complexity includes social risk factors, and we considered identifying patients dually eligible for Medicare and Medicaid, which we believe is a proxy for social risk factors. A ratio of beneficiaries seen by a MIPS eligible clinician who are dual eligible can be calculated using claims data based on the proportion of unique patients who are dually eligible for Medicare and full- and partial-benefit Medicaid (referred to herein as ''dual eligible status'') seen by the MIPS eligible clinician during the performance year among all unique Medicare beneficiaries seen during the performance year. Dual eligible Medicare beneficiaries are qualified to receive Medicare and Medicaid benefits. In the Physician and Other Supplier PUF, beneficiaries are classified as Medicare and Medicaid entitlement if in any month in the given calendar year they were receiving full or partial Medicaid benefits.[15] Dual eligibility has been used in the Medicare Advantage 5-star methodology [16] and stratification by proportion of dual eligibility status is proposed for the Hospital Readmissions Reduction Program (82 FR 19959 through 19961).

[14] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf.*

[15] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf.*

[16] Centers for Medicare & Medicaid Services. Medicare 2017 Part C & D Star Rating Technical Notes. Available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Part-C-and-D-Medicare-Star-Ratings-Data-v04-04-2017-.zip.*

We evaluated both indicators (average HCC risk score and proportion dual eligible status) using the 2015 Physician and Other Supplier PUF. We incorporated these factors into our scoring model that uses historical PQRS data to simulate scores for MIPS eligible clinicians including estimates for the quality, advancing care information, and improvement activities performance categories, and the small practice bonus that is proposed in section II.C.7.b.(1)(c) of this proposed rule. The scoring model is described in more detail in the regulatory impact analysis in section V.C. of this proposed rule. For HCC, we merged the average HCC risk score by NPI with each TIN/NPI in our population. We calculated a dual eligible ratio by taking a proportion of dual eligible beneficiaries and divided by total beneficiaries for each NPI. We created group level scores by taking an average of NPI scores weighted by the number of beneficiaries. We divided clinicians and groups into quartiles based on average HCC risk score and percent of duals. To assess whether there was a difference in MIPS simulated scores by these two variables, we analyzed the effect of average HCC risk score and dual eligible ratio separately for groups and individuals. When looking at individuals, we focused on individuals that reported 6 or more measures (removing individuals who reported no measures or who reported less than 6 measures). We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the required 6 measures, rather than differences in scores due to incomplete reporting.

We observed modest correlation between these two indicators. Using the Physician and Other Supplier PUF (after restricting to those clinicians that we estimate to be MIPS eligible in our scoring model described in section V.C of this proposed rule), the correlation coefficient for these two factors is 0.487 (some correlation is expected due to the inclusion of dual eligible status in the HCC risk model). The correlation between average HCC risk scores and proportion of patients with dual eligible status indicates that while there is overlap between these two indicators, they cannot be used interchangeably.

We also assessed the correlation of these indicators with MIPS final scores based on performance and the small practice bonus for MIPS eligible clinicians, as well as variations by practice size, submission mechanism, and specialty. Average MIPS simulated scores (prior to any complex patient bonus) varied from 82.73 (fourth HCC quartile, highest risk) to 87.14 (first HCC quartile, lowest risk) for group reporters, and from 82.36 (fourth HCC quartile, highest risk) to 86.39 (first HCC quartile, lowest risk) for individual reporters who reported 6 or more measures (see Table 34). When reviewing average HCC risk scores by practice size, we found that MIPS eligible clinicians in larger practices had slightly higher risk scores than those in small practices (average HCC risk score of 1.82 for practices with 100 or more clinicians, compared with 1.61 for practices with 1–15 clinicians) (see Table 35) and that the average HCC risk score varied by specialty, with nephrology having the highest average HCC risk score (3.05) and dermatology having the lowest (1.24). The average HCC risk score for family medicine was 1.58 (see Table 36).

We also ranked MIPS eligible clinicians by proportion of patients with dual eligibility (see Table 34). Performance for MIPS eligible clinicians ranged from 82.35 in the fourth dual quartile (highest proportion dual eligible patients) to 89.49 in the second dual quartile (second lowest proportion dual eligible patients) for group reporters. Performance for MIPS eligible clinicians reporting individually who reported 6 or more measures ranged from 83.08 in the fourth dual quartile (highest proportion dual eligible patients) to 86.80 in the first dual quartile (lowest proportion dual eligible patients).

TABLE 34—MIPS SIMULATED SCORE * BY HCC RISK QUARTILE AND DUAL ELIGIBLE RATIO QUARTILE

	Individuals with 6+ measures **	Group
HCC Quartile		
Quartile 1—Lowest Average HCC Risk Score	86.39	87.14
Quartile 2	84.89	88.41
Quartile 3	83.31	86.76
Quartile 4—Highest Average HCC Risk Score	82.36	82.73
Dual Eligible Ratio		
Quartile 1—Lowest Proportion of Dual Status	86.80	88.03
Quartile 2	83.76	89.49
Quartile 3	82.63	85.39
Quartile 4—Highest Proportion of Dual Status	83.08	82.35

* The simulated score includes estimated quality, advancing care information, and improvement activities performance categories without complex patient bonus. Simulated score does include small practice bonus proposed in II.C.7.b.(1)(c) of this proposed rule.

** We restricted this column to individuals who reported 6 or more measures to assess differences in performance for those who reported the required 6 measures and to not consider changes due to incomplete reporting.

TABLE 35—AVERAGE HCC RISK SCORE AND DUAL ELIGIBLE RATIO BY PRACTICE SIZE

Practice size	Average HCC risk score	Dual eligible ratio (%)
1–15 clinicians	1.61	24.90
16–24 clinicians	1.70	26.20
25–99 clinicians	1.72	27.50
100 or more clinicians	1.82	26.90
Total	1.75	26.60

TABLE 36—AVERAGE HCC RISK SCORE AND DUAL ELIGIBLE RATIO BY SPECIALTY

Specialty *	Average HCC risk score	Dual eligible ratio (%)
Total	1.75	26.60
Addiction Medicine	1.77	37.00
Allergy/Immunology	1.38	19.70
Anesthesiology	1.78	26.00
Anesthesiology Assistant	1.94	26.50
Cardiac Electrophysiology	1.85	23.20
Cardiac Surgery	1.93	25.10
Cardiovascular Disease (Cardiology)	1.85	25.30
Certified Clinical Nurse Specialist	1.78	31.20
Certified Registered Nurse Anesthetist (CRNA)	1.77	25.50
Chiropractic	1.27	19.10
Clinic or Group Practice	1.57	30.60
Colorectal Surgery (Proctology)	1.70	22.10
Critical Care (Intensivists)	2.06	28.50
Dermatology	1.24	11.90
Diagnostic Radiology	1.78	26.50
Emergency Medicine	1.94	34.10
Endocrinology	1.78	24.70
Family Medicine *	1.58	25.80
Gastroenterology	1.70	24.20
General Practice	1.60	35.80
General Surgery	1.83	27.10
Geriatric Medicine	1.93	29.60
Geriatric Psychiatry	1.92	39.30
Gynecological Oncology	1.76	24.20
Hand Surgery	1.39	17.80
Hematology	1.95	25.80
Hematology-Oncology	1.92	24.90
Hospice and Palliative Care	1.93	26.90
Infectious Disease	2.35	31.60
Internal Medicine	1.84	28.10
Interventional Cardiology	1.79	22.90
Interventional Pain Management	1.50	26.90
Interventional Radiology	2.18	28.80
Maxillofacial Surgery	1.90	30.20
Medical Oncology	1.94	23.50
Nephrology	3.05	33.00
Neurology	1.79	27.40
Neuropsychiatry	1.76	30.30
Neurosurgery	1.68	24.70
Nuclear Medicine	1.91	26.10
Nurse Practitioner	1.78	28.60
Obstetrics & Gynecology	1.63	26.20
Ophthalmology	1.37	18.70
Optometry	1.33	24.80
Oral Surgery (Dentist only)	1.82	29.20
Orthopedic Surgery	1.44	20.50
Osteopathic Manipulative Medicine	1.62	29.70
Otolaryngology	1.50	21.10
Pain Management	1.57	29.50
Pathology	1.71	23.70
Pediatric Medicine	1.95	31.10
Peripheral Vascular Disease	1.83	23.10
Physical Medicine and Rehabilitation	1.76	27.00
Physician Assistant	1.69	26.40
Physician, Sleep Medicine	1.70	23.20
Plastic and Reconstructive Surgery	1.74	23.60
Podiatry	1.72	27.70
Preventive Medicine	1.80	27.60
Psychiatry	1.80	39.50
Pulmonary Disease	2.00	27.20
Radiation Oncology	1.79	22.20
Rheumatology	1.65	23.40
Sports Medicine	1.54	22.70
Surgical Oncology	1.92	25.10
Thoracic Surgery	1.94	26.30
Urology	1.56	20.30
Vascular Surgery	2.22	26.80

* Specialty descriptions as self-reported on Part B claims. Note that all categories are mutually exclusive, including General Practice and Family Practice. 'Family Medicine' is used here for physicians listed as 'Family Practice' in Part B claims.

Based on our assessment of these two indicators, we generally see high average simulated scores [17] that are above 80 points for each quartile based on average HCC risk score or proportion of dual status patients (see Table 34). As discussed in II.C.8.d. of this proposed rule, 70 points is the proposed additional performance threshold at which MIPS eligible clinicians can receive the additional adjustment factor for exceptional performance. However, even though the simulated scores are high, we also generally see a very modest decrease in simulated scores of 4.0 points (for individuals who report 6 or more measures) and 4.4 points (for groups) from the top quartile to the bottom quartile for the average patient HCC risk score and from 3.7 (for individuals who report 6 or more measures) and 5.7 points (for groups) from the top quartile to the bottom quartile for dual eligible ratio. While we are transitioning into MIPS and evolving our scoring policies, we want to ensure safeguards and access for these vulnerable patients; therefore, we are proposing to apply a small complex patient bonus to final scores used for the 2020 MIPS payment year. As we stated earlier, we intend to start with one dimension of patient complexity for simplicity. For the 2020 MIPS payment year, we are proposing a complex patient bonus based on the average HCC risk score because this is the indicator that clinicians are familiar with from the VM.

We propose at § 414.1380(c)(3) to add a complex patient bonus to the final score for the 2020 MIPS payment year for MIPS eligible clinicians that submit data (as explained below) for at least one performance category. We propose at § 414.1380(c)(3)(i) to calculate an average HCC risk score, using the model adopted under section 1853 of the Act for Medicare Advantage risk adjustment purposes, for each MIPS eligible clinician or group, and to use that average HCC risk score as the complex patient bonus. We would calculate the average HCC risk score for a MIPS eligible clinician or group by averaging HCC risk scores for beneficiaries cared for by the MIPS eligible clinician or clinicians in the group during the second 12-month segment of the eligibility period, which spans from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period in the next calendar year (September 1, 2017 to August 31, 2018 for the 2018 MIPS performance period) as described in section II.C.3.c. of this proposed rule. We propose the second 12-month segment of the eligibility period to align with other MIPS policies and to ensure we have sufficient time to determine the necessary calculations. The second period 12-month segment overlaps 8-months with the MIPS performance period which means that many of the patients in our complex patient bonus would have been cared for by the clinician, group, virtual group or APM Entity during the MIPS performance period.

HCC risk scores for beneficiaries would be calculated based on the calendar year immediately prior to the performance period. For the 2018 MIPS performance period, the HCC risk scores would be calculated based on beneficiary services from the 2017 calendar year. We chose this approach because CMS uses prior year diagnoses to set Medicare Advantage rates prospectively every year and has employed this approach in the VM (77 FR 69317–8). Additionally, this approach mitigates the risk of ''upcoding'' to get higher expected costs, which could happen if concurrent risk adjustments were incorporated. We realize using the 2017 calendar year to assess beneficiary HCC risk scores overlaps by 4-months with the 12-month data period to identify beneficiaries (which is September 1, 2017 to August 31, 2018 for the 2018 MIPS performance period); however, we annually calculate the beneficiary HCC risk score and use it for multiple purposes (like the Physician and Other Supplier PUF).

For MIPS APMs and virtual groups, we propose at § 414.1380(c)(3)(ii) to use the beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively, as the complex patient bonus. We would calculate the weighted average by taking the sum of the individual clinician's (or TIN's as appropriate) average HCC risk score multiplied by the number of unique beneficiaries cared for by the clinician and then divide by the sum of the beneficiaries cared for by each individual clinician (or TIN as appropriate) in the APM Entity or virtual group.

We propose at § 414.1380(c)(3)(iii) that the complex patient bonus cannot exceed 3 points. This value was selected because the differences in performance we observed between simulated scores between the first and fourth quartiles of average HCC risk scores was approximately 4 points for individuals and approximately 5 points for groups. We considered whether we should apply a set number of points to those in a specific quartile (for example, for the highest risk quartile only), but did not want to restrict the bonus to only certain MIPS eligible clinicians. Rather than assign points based on quartile, we believed that adding the average HCC risk score directly to the final score would achieve our goal of accounting for patient complexity without masking low performance and does provide a modest effect on the final score. The 95th percentile of HCC values for individual clinicians was 2.91 which we rounded to 3 for simplicity. We believe applying this bonus to the final score is appropriate because caring for complex and vulnerable patients can affect all aspects of a practice and not just specific performance categories. It may also create a small incentive to provide access to complex patients.

Finally, we propose that the MIPS eligible clinician, group, virtual group or APM Entity must submit data on at least one measure or activity in a performance category during the performance period to receive the complex patient bonus. Under this proposal, MIPS eligible clinicians would not need to meet submissions requirements for the quality performance category in order to receive the bonus (they could instead submit improvement activities or advancing care information measures only or submit fewer than the required number of measures for the quality performance category).

Based on our data analysis, we estimate that this bonus on average would range from 1.16 points in the first quartile based on HCC risk scores to 2.49 points in the fourth quartile for individual reporters submitting 6 or more measures, and 1.26 points in the first quartile to 2.23 points in the fourth quartile for group reporters. For example, a MIPS eligible clinician with a final score of 55.11 with an average HCC risk score of 2.01 would receive a final score of 57.12. We propose in section II.C.7.b.(2) of this proposed rule that if the result of the calculation is greater than 100 points, then the final score would be capped at 100 points.

We also seek comment on an alternative complex patient bonus methodology, similarly for the 2020 MIPS payment year only. Under the alternative, we would apply a complex patient bonus based on a ratio of patients who are dual eligible, because we believe that dual eligible status is a common indicator of social risk for

[17] Scores are simulated prior to any complex patient bonus.

which we currently have data available. We believe the advantage of this option is its relative simplicity and that it creates a direct incentive to care for dual eligible patients, who are often medically complex and have concurrent social risk factors. In addition, whereas the HCC risk scores rely on the diagnoses a beneficiary receives which could be impacted by variations in coding practices among clinicians, the dual eligibility ratio is not impacted by variations in coding practices. For this alternative option, we would calculate a dual eligible ratio (including both full and partial Medicaid beneficiaries) for each MIPS eligible clinician based on the proportion of unique patients who have dual eligible status seen by the MIPS eligible clinician among all unique patients seen during the second 12-month segment of the eligibility period, which spans from the last 4 months of a calendar year 1 year prior to the performance period followed by the first 8 months of the performance period.

For MIPS APMs and virtual groups, we would use the average dual eligible patient ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively.

Under this alternative option, we would identify dual eligible status (numerator of the ratio) using data on dual-eligibility status sourced from the state Medicare Modernization Act (MMA) files, which are files each state submits to CMS with monthly Medicaid eligibility information. We would use dual-eligibility status data from the state MMA files because it is the best available data for identifying dual eligible beneficiaries. Under this alternative option, an individual would be counted as a full-benefit or partial-benefit dual patient if the beneficiary was identified as a full-benefit or partial-benefit dual in the state MMA files at the conclusion of the second 12-month segment of the eligibility determination period.

We would define the proportion of full benefit or partial dual eligible beneficiaries as the proportion of dual eligible patients among all unique Medicare patients seen by the MIPS eligible clinician or group during the second 12-month segment of the eligibility period which spans from the last 4 months of a calendar year prior to the performance period followed by the first 8 months of the performance period in the next calendar year (September 1, 2017 to August 31, 2018 for the 2018 MIPS performance period) as described in section II.C.3.c. of this proposed rule, to identify MIPS eligible clinicians for calculation of the complex patient bonus. This date range aligns with the second low-volume threshold determination and also represents care provided during the performance period.

We would propose to multiply the dual eligible ratio by 5 points to calculate a complex patient bonus for each MIPS eligible clinician. For example, a MIPS eligible clinician who sees 400 patients with dual eligible status out of 1000 total Medicare patients seen during the second 12-month segment of the eligibility period would have a complex patient ratio of 0.4, which would be multiplied by 5 points for a complex patient bonus of 2 points toward the final score. We believe this approach is simple to explain and would be available to all clinicians who care for dual eligible beneficiaries. We also believe a complex patient bonus ranging from 1 to 5 points (with most MIPS eligible clinicians receiving a bonus between 1 and 3 points) is appropriate because, in our analysis, we estimated differences in performance between the 1st and 4th quartiles of dual eligible ratios to be approximately 3 points for individuals and approximately 6 points for groups. A bonus of less than 5 points would help to mitigate the impact of caring for patients with social risk factors while not masking poor performance. Using this approach, we estimate that the bonus would range from 0.45 (first dual quartile) to 2.42 (fourth dual quartile) for individual reporters, and from 0.63 (first dual quartile) to 2.19 (fourth dual quartile) for group reporters. Under this alternative option, we would also include the complex patient bonus in the calculation of the final score. Again, we propose in section II.C.7.b.(2) of this proposed rule that if the result of the calculation is greater than 100 points, then the final score would be capped at 100 points. We seek comments on our proposed bonus for complex patients based on average HCC risk scores, and our alternative option using a ratio of dual eligible patients in lieu of average HCC risk scores. We reiterate that the complex patient bonus is intended to be a short-term solution, which we plan to revisit on an annual basis, to incentivize clinicians to care for patients with medical complexity. We may consider alternate adjustments in future years after methods that more fully account for patient complexity in MIPS have been developed. We also seek comments on alternative methods to construct a complex patient bonus.

(c) Small Practice Bonus for the 2020 MIPS Payment Year

Eligible clinicians and groups who work in small practices are a crucial part of the health care system. The Quality Payment Program provides options designed to make it easier for these MIPS eligible clinicians and groups to report on performance and quality and participate in advanced alternative payment models for incentives. We have heard directly from clinicians in small practices that they face unique challenges related to financial and other resources, environmental factors, and access to health information technology. We heard from many commenters that the Quality Payment Program advantages large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS. Based on our scoring model, which is described in the regulatory impact analysis in section V.C. of this proposed rule, practices with more than 100 clinicians may perform better in the Quality Payment Program, on average compared to smaller practices. We believe this trend is due primarily to two factors: Participation rates and submission mechanism. Based on the most recent PQRS data available, practices with 100 or more MIPS eligible clinicians have participated in the PQRS at a higher rate than small practices (99.4 percent compared to 69.7 percent, respectively). As we indicate in our regulatory impact analysis in section V.C. of this proposed rule, we believe participation rates based only on historic 2015 quality data submitted under PQRS significantly underestimate the expected participation in MIPS particularly for small practices. Therefore, we have modeled the regulatory impact analysis using minimum participation assumptions of 80 percent and 90 percent participation for each practice size category (1–15 clinicians, 16–24 clinicians, 25–99 clinicians, and 100 or more clinicians). However, even with these enhanced participation assumptions, MIPS eligible clinicians in small practices would have lower participation than MIPS eligible clinicians in larger practices as 80 or 90 percent participation is still much lower than the 99.4 percent participation for MIPS eligible clinicians in practices with 100 or more clinicians.

In addition, practices with 100 or more MIPS eligible clinicians are more likely to report as a group, rather than individually, which reduces burden to individuals within those practices due

to the unified nature of group reporting. Specifically, 63.1 percent of practices with 100 or more MIPS eligible clinicians are reporting via CMS Web Interface (either through the Shared Savings Program or as a group practice) compared to 20.5 percent of small practices (the CMS Web Interface reporting mechanism is only available to small practices participating in the Shared Saving Program or Next Generation ACO Model.) [18]

These two factors have financial implications based on the MIPS scoring model described in section V.C. of this proposed rule. Looking at the combined impact performance, we see consistent trends for small practices in various scenarios. A combined impact of performance measurement looks at the aggregate net percent change (the combined impact of MIPS negative and positive adjustments in the final score). In analyzing the combined impact performance, we see MIPS eligible clinicians in small practices consistently have a lower combined impact performance than larger practices based on actual historical data and after we apply the 80 and 90 percent participation assumptions.

Due to these challenges, we believe an adjustment to the final score for MIPS eligible clinicians in small practices (referred to herein as the ''small practice bonus'') is appropriate to recognize these barriers and to incentivize MIPS eligible clinicians in small practices to participate in the Quality Payment Program and to overcome any performance discrepancy due to practice size. To receive the small practice bonus, we propose that the MIPS eligible clinician must participate in the program by submitting data on at least one performance category in the 2018 MIPS performance period. Therefore, MIPS eligible clinicians would not need to meet submission requirements for the quality performance category in order to receive the bonus (they could instead submit improvement activities or advancing care information measures only or submit fewer than the required number of measures for the quality performance category). Additionally, we propose that group practices, virtual groups, or APM Entities that consist of a total of 15 or fewer clinicians may receive the small practice bonus.

We propose at § 414.1380(c)(4) to add a small practice bonus of five points to the final score for MIPS eligible clinicians who participate in MIPS for the 2018 MIPS performance period and are in small practices or virtual groups or APM entities with 15 or fewer clinicians (the entire virtual group or APM entity combined must include 15 or fewer clinicians to qualify for the bonus). We believe a bonus of 5 points is appropriate to acknowledge the challenges small practices face in participating in MIPS, and to help them achieve the performance threshold proposed at section II.C.8.c. of this proposed rule at 15 points for the 2020 MIPS payment year, as this bonus represents one-third of the total points needed to meet or exceed the performance threshold and receive a neutral to positive payment adjustment. With a small practice bonus of 5 points, small practices could achieve this performance threshold by reporting 2 quality measures or 1 quality measure and 1 improvement activity.[19] We believe that a higher bonus (for example, a bonus that would meet or exceed the performance threshold) is not ideal because it might discourage small practices from actively participating in MIPS or could mask poor performance. We propose in section II.C.7.b.(2) of this proposed rule that if the result of the calculation is greater than 100 points, then the final score would be capped at 100 points.

This bonus is intended to be a short-term strategy to help small practices transition to MIPS, therefore, we are proposing the bonus only for the 2018 MIPS performance period (2020 MIPS payment year) and will assess on an annual basis whether to continue the bonus and how the bonus should be structured.

We are inviting public comment on our proposal to apply a small practice bonus for the 2020 MIPS payment year.

We also considered applying a bonus for MIPS eligible clinicians that practice in either a small practice or a rural area. However, on average, we saw less than a one point difference between scores for MIPS eligible clinicians who practice in rural areas and those who do not. Therefore, we are not proposing to extend the final score bonus to those who practice in a rural area, but plan to continue to monitor the Quality Payment Program's impacts on the performance of those who practice in rural areas. We also seek comment on the application of a rural bonus in the future, including available evidence demonstrating differences in clinician performance based on rural status. If we implement a bonus for practices located in rural areas, we would use the definition for rural specified in section II.C.1. of this proposed rule for individuals and groups (including virtual groups).

(2) Final Score Calculation

With the proposed addition of the complex patient and small practice bonuses, we propose to use the formula at § 414.1380(c) to calculate the final score for all MIPS eligible clinicians, groups, virtual groups, and MIPS APMs starting with the 2020 MIPS payment year.

We propose to revise the final score calculation at § 414.1380(c) to reflect this updated formula. We also propose to revise the policy finalized in the CY 2017 Quality Payment Program final rule to assign MIPS eligible clinicians with only 1 scored performance category a final score that is equal to the performance threshold (81 FR 77326 through 77328) (we note that we inadvertently failed to codify this policy in § 414.1380(c)). We are proposing this revision to the policy to account for our proposal in section II.C.7.b.(3)(c) of this proposed rule for extreme and uncontrollable circumstances which, if finalized, could result in a scenario where a MIPS eligible clinician is not scored on any performance categories. To reflect this proposal, we propose to add to § 414.1380(c) that a MIPS eligible clinician with fewer than 2 performance category scores would receive a final score equal to the performance threshold.

With the proposed addition of the complex patient and small practice bonuses, we also propose to strike the following phrase from the final score definition at § 414.1305: ''The final score is the sum of each of the products of each performance category score and each performance category's assigned weight, multiplied by 100.'' We believe this portion of the definition would be incorrect and redundant of the proposed revised regulation at § 414.1380(c).

We invite public comment on the proposed final score methodology and associated revisions to regulation text.

[18] Groups must have at least 25 clinicians to participate in Web Interface.

[19] Assuming the small practice did not submit advancing care information and applied for the hardship exception and had the advancing care information performance category weight redistributed to quality, the small practice would have a final score with 85 percent weight from the quality performance category score and 15 percent from improvement activities. With the proposed scoring for small practices, submitting one measure one time would provide at least 3 measure achievement points out of 60 total available measure points. With 85 percent quality performance category weight, each quality measure would be worth at least 4.25 point towards the final score. ((3/60) × 85% × 100= 4.25 points). For improvement activities, each medium weighted activity is worth 20 out of 40 possible points which translates to 7.5 points to the file score. (20/40) × 15% × 100 = 7.5 points).

(3) Final Score Performance Category Weights

(a) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category, 30 percent for the cost performance category, 25 percent for the advancing care information performance category, and 15 percent for the improvement activities performance category. However, that section also specifies different weightings for the quality and cost performance categories for the first and second years for which the MIPS applies to payments. Section 1848(q)(5)(E)(i)(II)(bb) of the Act specifies that for the transition year, not more than 10 percent of the final score will be based on the cost performance category, and for the 2020 MIPS payment year, not more than 15 percent will be based on the cost performance category. Under section 1848(q)(5)(E)(i)(I)(bb) of the Act, the weight of the quality performance category for each of the first 2 years will increase by the difference of 30 percent minus the weight specified for the cost performance category for the year.

In the CY 2017 Quality Payment Program final rule, we established the weights of the cost performance category as 10 percent of the final score (81 FR 77166) and the quality performance category as 50 percent of the final score (81 FR 77100) for the 2020 MIPS payment year. However, we are proposing in section II.C.6.d. of this proposed rule to change the weight of the cost performance category to zero percent and in section II.C.6.b. of this proposed rule to change the weight of the quality performance category to 60 percent for the 2020 MIPS payment year. We refer readers to sections II.C.6.b. and II.C.6.d. of this proposed rule for further information on the policies related to the weight of the quality and cost performance categories, including our rationale for our proposed weighting for each category.

As specified in section 1848(q)(5)(E)(i) of the Act, the weights for the other performance categories are 25 percent for the advancing care information performance category and 15 percent for the improvement activities performance category. Section 1848(q)(5)(E)(ii) of the Act provides that in any year in which the Secretary estimates that the proportion of eligible professionals (as defined in section 1848(o)(5) of the Act) who are meaningful EHR users (as determined in section 1848(o)(2) of the Act) is 75 percent or greater, the Secretary may reduce the applicable percentage weight of the advancing care information performance category in the final score, but not below 15 percent. For more on our policies concerning section 1848(q)(5)(E)(ii) of the Act and a review of our proposal for reweighting the advancing care information performance category in the event that the proportion of MIPS eligible clinicians who are meaningful EHR users is 75 percent or greater starting with the 2019 MIPS performance period, we refer readers to section II.C.6.f.(5) of this proposed rule.

Table 37 summarizes the weights specified for each performance category under section 1848(q)(5)(E)(i) of the Act and in accordance with our policies in the CY 2017 Quality Payment Program final rule as codified at §§ 414.1380(c)(1), 414.1330(b), 414.1350(b), 414.1355(b), and 414.1375(a), and with our proposals in section II.C.6. of this proposed rule.

TABLE 37—FINALIZED AND PROPOSED WEIGHTS BY MIPS PERFORMANCE CATEGORY *

Performance category	Transition year (final) (%)	2020 MIPS payment year (proposed) (%)	2021 MIPS payment year and beyond (final) (%)
Quality	60	60	30
Cost	0	0	30
Improvement Activities	15	15	15
Advancing Care Information**	25	25	25

* In sections II.C.6.b. and II.C.6.c., we propose to maintain the same weights from the transition year for the 2020 MIPS payment year for quality and cost (60 percent and zero percent, respectively).

**As described in section II.C.6.f. of this proposed rule, the weight for advancing care information could decrease (not below 15 percent) starting with the 2021 MIPS payment year if the Secretary estimates that the proportion of physicians who are meaningful EHR users is 75 percent or greater.

(b) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable and for each measure and activity based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. For the 2020 MIPS payment year, we propose to assign a scoring weight of zero percent to a performance category and redistribute its weight to the other performance categories in the following scenarios.

For the quality performance category, we propose that having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the MIPS eligible clinician. Based on the volume of measures available to MIPS eligible clinicians via the multiple submission mechanisms, we generally believe there will be at least one quality measure applicable and available to every MIPS eligible clinician. Given that we generally believe there will be at least one quality measure applicable and available to every MIPS eligible clinician, if we receive no quality performance category submission from a MIPS eligible clinician, the MIPS eligible clinician generally will receive a performance category score of zero (or slightly above zero if the all-cause hospital readmission measure applies because the clinician submits data for a performance category other than the quality performance category).[20]

[20] As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77300), groups of 16 or more eligible clinicians that meet the applicable case minimum requirement are automatically scored on the all-cause readmission measure, even if they do not submit any other data under the

Continued

However, as described in section II.C.7.a.(2)(e) of this proposed rule, there may be rare instances that we believe could affect only a very limited subset of MIPS eligible clinicians (as well as groups and virtual groups) that may have no quality measures available and applicable and for whom we receive no quality performance category submission (and for whom the all-cause hospital readmission measure does not apply). In those instances, we would not be able to calculate a quality performance category percent score.

The proposed quality performance category scoring policies for the 2020 MIPS payment year continue many of the special scoring policies from the transition year which would enable us to determine a quality performance category percent score whenever a MIPS eligible clinician has submitted at least 1 quality measure. In addition, MIPS eligible clinicians that do not submit quality measures when they have them available and applicable would receive a quality performance category percent score of zero percent. It is only in the rare scenarios when we determine that a MIPS eligible clinician does not have any relevant quality measures available to report or the MIPS eligible clinician is approved for reweighting the quality performance category based on extreme and uncontrollable circumstances as proposed in section II.C.7.b.(3)(c) of this proposed rule, that we would reweight the quality performance category. Therefore, we continue to believe that we will not be able to calculate a score for the quality performance category only in the rare scenarios when a MIPS eligible clinician does not have any relevant quality measures available to report.

For the cost performance category, we continue to believe that having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician, and that MIPS eligible clinicians who are not attributed enough cases to be reliably measured should not be scored for the cost performance category (81 FR 77322 through 77323). We established a policy that if a MIPS eligible clinician is not attributed a sufficient number of cases for a measure (in other words, has not met the required case minimum for the measure), or if a measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). If we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score. Because we have proposed in section II.C.6.d. of this proposed rule to set the weight of the cost performance category to zero percent of the final score for the 2020 MIPS payment year, we are not proposing to redistribute the weight of the cost performance category to any other performance categories for the 2020 MIPS payment year. In the event we do not finalize this proposal, we are proposing to redistribute the weight of the cost performance category as described in section II.C.7.b.(3)(d) of this proposed rule.

For the improvement activities performance category, we believe that all MIPS eligible clinicians will have sufficient activities applicable and available; however, as discussed in section II.C.7.b.(3)(c) of this proposed rule, we believe there are limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities. Barring these circumstances, we are not proposing any changes that would affect our ability to calculate an improvement activities performance category score.

We refer readers to section II.C.6.f. of this proposed rule for a detailed discussion of our proposals and policies under which we would not score the advancing care information performance category and would assign a weight of zero percent to that category for a MIPS eligible clinician.

We invite public comment on our interpretation of sufficient measures available and applicable in the performance categories.

(c) Extreme and Uncontrollable Circumstances

In the CY 2017 Quality Payment Program final rule (81 FR 77241 through 77243), we discussed our belief that extreme and uncontrollable circumstances, such as a natural disaster in which an EHR or practice location is destroyed, can happen at any time and are outside a MIPS eligible clinician's control. We stated that if a MIPS eligible clinician's CEHRT is unavailable as a result of such circumstances, then the measures specified for the advancing care information performance category may not be available for the MIPS eligible clinician to report. We established a policy allowing a MIPS eligible clinician affected by extreme and uncontrollable circumstances to submit an application to us to be considered for reweighting of the advancing care information performance category under section 1848(q)(5)(F) of the Act. Although we are proposing in section II.C.6.f. of this proposed rule to use the authority in the last sentence of section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as the authority for this policy, rather than section 1848(q)(5)(F) of the Act, we continue to believe that extreme and uncontrollable circumstances could affect the availability of a MIPS eligible clinician's CEHRT and the measures specified for the advancing care information performance category.

While we did not propose or finalize a similar reweighting policy for other performance categories in the transition year, we believe a similar reweighting policy may be appropriate for the quality, cost, and improvement activities performance categories beginning with the 2020 MIPS payment year. For these performance categories, we propose to define ''extreme and uncontrollable circumstances'' as rare (that is, highly unlikely to occur in a given year) events entirely outside the control of the clinician and of the facility in which the clinician practices that cause the MIPS eligible clinician to not be able to collect information that the clinician would submit for a performance category or to submit information that would be used to score a performance category for an extended period of time (for example, 3 months could be considered an extended period of time with regard to information a clinician would collect for the quality performance category). For example, a tornado or fire destroying the only facility in which a clinician practices likely would be considered an ''extreme and uncontrollable circumstance;'' however, neither the inability to renew a lease—even a long or extended lease—nor a facility being found not compliant with federal, state, or local building codes or other requirements would be considered ''extreme and uncontrollable circumstances.'' We propose that we would review both the circumstances and the timing independently to assess the availability and applicability of measures and activities independently for each performance category. For example, in 2018 the performance period for improvement activities is only 90 days, whereas it is 12 months for the quality performance category, so an issue lasting 3 months may have more impact on the availability of measures for the quality performance category than for the improvement activities performance category, because

quality performance category, provided that they submit data under one of the other performance categories. If such groups do not submit data under any performance category, the readmission measure is not scored.

the MIPS eligible clinician, conceivably, could participate in improvement activities for a different 90-day period.

We believe that extreme and uncontrollable circumstances, such as natural disasters, may affect a clinician's ability to access or submit quality measures via all submission mechanisms (effectively rendering the measures unavailable to the clinician) as well as the availability of numerous improvement activities. In addition, damage to a facility where care is provided due to a natural disaster, such as a hurricane, could result in practice management and clinical systems that are used for the collection or submission of data to be down, thus impacting a clinician's ability to submit necessary information via Qualified Registry, QCDR, CMS Web Interface, or claims. This policy would not include issues that third party intermediaries, such as EHRs, Qualified Registries, or QCDRs, might have submitting information to MIPS on behalf of a MIPS eligible clinician. Instead, this policy is geared towards events, such as natural disasters, that affect the MIPS eligible clinician's ability to submit data to the third party intermediary, which in turn, could affect the ability of the clinician (or the third party intermediary acting on their behalf) to successfully submit measures and activities to MIPS.

We also propose to use this policy for measures which we derive from claims data, such as the all-cause hospital readmission measure and the cost measures. Other programs, such as the Hospital VBP Program, allow hospitals to submit exception applications when ''a hospital is able to continue to report data on measures . . . but can demonstrate that its Hospital VBP Program measure rates are negatively impacted as a result of a natural disaster or other extraordinary circumstance and, as a result, the hospital receives a lower value-based incentive payment'' (78 FR 50705). For the Hospital VBP Program, we ''interpret[ed] the minimum numbers of cases and measures requirement in the Act to enable us to not score . . . all applicable quality measure data from a performance period and, thus, exclude the hospital from the Hospital VBP Program for a fiscal year during which the hospital has experienced a disaster or other extraordinary circumstance'' (78 FR 50705). Hospitals that request and are granted an exception are exempted from the Program entirely for the applicable year.

For the 2020 MIPS payment year, we would score quality measures and assign points even for those clinicians who do not meet the case minimums for the quality measures they submit. However, we established a policy not to score a cost measure unless a MIPS eligible clinician has met the required case minimum for the measure (81 FR 77323), and not to score administrative claims measures, such as the all-cause hospital readmission measure, if they cannot be reliably scored against a benchmark (81 FR 77288 through 77289). Even if the required case minimums have been met and we are able to reliably calculate scores for the measures that are derived from claims, we believe a MIPS eligible clinician's performance on those measures could be adversely impacted by a natural disaster or other extraordinary circumstance, similar to the issues we identified for the Hospital VBP Program. For example, the claims data used to calculate the cost measures or the all-cause hospital readmission measure could be significantly affected if a natural disaster caused wide-spread injury or health problems for the community, which could not have been prevented by high-value healthcare. In such cases, we believe that the measures are available to the clinician, but are likely not applicable, because the extreme and uncontrollable circumstance has disrupted practice and measurement processes. Therefore, we believe an approach similar to Hospital VBP Program is warranted under MIPS, and we are proposing that we would exempt a MIPS eligible clinician from all quality and cost measures calculated from administrative claims data if the clinician is granted an exception for the respective performance categories based on extreme and uncontrollable circumstances.

Beginning with the 2020 MIPS payment year, we propose that we would reweight the quality, cost, and/or improvement activities performance categories if a MIPS eligible clinician, group, or virtual group's request for a reweighting assessment based on extreme and uncontrollable circumstances is granted. We propose that MIPS eligible clinicians could request a reweighting assessment if they believe extreme and uncontrollable circumstances affect the availability and applicability of measures for the quality, cost, and improvement activities performance categories. To the extent possible, we would seek to align the requirements for submitting a reweighting assessment for extreme and uncontrollable circumstances with the requirements for requesting a significant hardship exception for the advancing care information performance category. For example, we propose to adopt the same deadline (December 31, 2018 for the 2018 MIPS performance period) for submission of a reweighting assessment (see section II.C.6.f. of this proposed rule), and we would encourage the requests to be submitted on a rolling basis. We propose the reweighting assessment must include the nature of the extreme and uncontrollable circumstance, including the type of event, date of the event, and length of time over which the event took place, performance categories impacted, and other pertinent details that impacted the ability to report on measures or activities to be considered for reweighting of the quality, cost, or improvement activities performance categories (for example, information detailing how exactly the event impacted availability and applicability of measures). If we finalize the policy to allow reweighting based on extreme and uncontrollable circumstances beginning with the 2020 MIPS payment year, we would specify the form and manner in which these reweighting applications must be submitted outside of the rulemaking process after the final rule is published.

For virtual groups, we propose to ask the virtual group to submit a reweighting assessment for extreme and uncontrollable circumstances similar to groups, and we would evaluate whether sufficient measures and activities are applicable and available to the majority of TINs in the virtual group. We are proposing that a majority of TINs in the virtual group would need to be impacted before we grant an exception. We still find it important to measure the performance of virtual group members unaffected by an extreme and uncontrollable circumstance even if some of the virtual group's TINs are affected.

We also seek comment on what additional factors we should consider for virtual groups. This reweighting assessment due to extreme and uncontrollable circumstances for the quality, cost, and improvement activities would not be available to APM Entities in the APM scoring standard for the following reasons. First, all MIPS eligible clinicians scored under the APM scoring standard will automatically receive an improvement activities category score based on the terms of their participation in a MIPS APM and need not report anything for this performance category. Second, the cost performance category has no weight under the APM scoring standard. Finally, for the quality performance category, each MIPS APM has its own rules related to quality measures and we believe any decisions related to

availability and applicability of measures should reside within the model. As noted in II.C.6.g.(2)(d) of this proposed rule, MIPS APM entities would be able to request reweighting of the advancing care information performance category.

If we finalize these proposals for reweighting the quality, cost, and improvement activities performance categories based on extreme and uncontrollable circumstances, then it would be possible that one or more of these performance categories would not be scored and would be weighted at zero percent of the final score for a MIPS eligible clinician. We propose to assign a final score equal to the performance threshold if fewer than two performance categories are scored for a MIPS eligible clinician. This is consistent with our policy finalized in the CY 2017 Quality Payment Program final rule that because the final score is a composite score, we believe the intention of section 1848(q)(5) of the Act is for MIPS eligible clinicians to be scored based on multiple performance categories (81 FR 77326 through 77328).

We request comment on our extreme and uncontrollable circumstances proposals. We also seek comment on the types of the extreme and uncontrollable circumstances we should consider for this policy given the general parameters we describe in this section.

(d) Redistributing Performance Category Weights

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1380(c)(2) that we will assign different scoring weights for the performance categories if we determine there are not sufficient measures and activities applicable and available to MIPS eligible clinicians (81 FR 77327). We also finalized a policy to assign MIPS eligible clinicians with only one scored performance category a final score that is equal to the performance threshold, which means the clinician would receive a MIPS payment adjustment factor of zero percent for the year (81 FR 77326 through 77328). We are proposing in section II.C.7.b.(2) of this proposed rule to refine this policy such that a MIPS eligible clinician with fewer than 2 performance category scores would receive a final score equal to the performance threshold. This refinement is to account for our proposal in section II.C.7.b.(3)(c) of this proposed rule for extreme and uncontrollable circumstances which, if finalized, could result in a scenario where a MIPS eligible clinician is not scored on any performance categories. We refer readers to the CY 2017 Quality Payment Program final rule for a description of our policies for redistributing the weights of the performance categories (81 FR 77325 through 77329). For the 2020 MIPS payment year, we propose to redistribute the weights of the performance categories in a manner that is similar to the transition year. However, we are also proposing new scoring policies to incorporate our proposals for extreme and uncontrollable circumstances.

In section II.C.6.f. of this proposed rule, we are proposing to use the authority in the last sentence of section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as the authority for certain policies under which we would assign a scoring weight of zero percent for the advancing care information performance category, and to amend § 414.1380(c)(2) to reflect our proposals. We are not, however, proposing substantive changes to the policy established in the CY 2017 Quality Payment Program final rule to redistribute the weight of the advancing care information performance category to the other performance categories for the transition year (81 FR 77325 through 77329).

For the 2020 MIPS payment year, if we assign a weight of zero percent for the advancing care information performance category for a MIPS eligible clinician, we propose to continue our policy from the transition year and redistribute the weight of the advancing care information performance category to the quality performance category (assuming the quality performance category does not qualify for reweighting). We believe redistributing the weight of the advancing care information performance category to the quality performance category (rather than redistributing to both the quality and improvement activities performance categories) is appropriate because MIPS eligible clinicians have more experience reporting quality measures through the PQRS program, and measurement in this performance category is more mature.

If we do not finalize our proposal at section II.C.6.d. of this proposed rule to weight the cost performance category at zero percent (which means the weight of the cost performance category is greater than zero percent), then we propose to not redistribute the weight of any other performance categories to the cost performance category. We believe this is consistent with our policy of introducing cost measurement in a deliberate fashion and recognition that clinicians are more familiar with other elements of MIPS. In the rare and unlikely scenario where a MIPS eligible clinician qualifies for reweighting of the quality performance category percent score (because there are not sufficient quality measures applicable and available to the clinician or the clinician is facing extreme and uncontrollable circumstances) and the MIPS eligible clinician is eligible to have the advancing care information performance category reweighted to zero and the MIPS eligible clinician has sufficient cost measures applicable and available to have a cost performance category percent score that is not reweighted, then we would redistribute the weight of the quality and advancing care information performance categories to the improvement activities performance category and would not redistribute the weight to the cost performance category. If we finalize the cost performance category weight at zero percent for the 2020 MIPS payment year, then we would set the final score at the performance threshold because the final score would be based on improvement activities which would not be a composite of two or more performance category scores.

For the 2020 MIPS payment year, if we do not finalize the proposal to set the cost performance category a zero percent weight, and if a MIPS eligible clinician does not receive a cost performance category percent score because there are not sufficient cost measures applicable and available to the clinician or the clinician is facing extreme and uncontrollable circumstances, we propose to redistribute the weight of the cost performance category to the quality performance category. In the rare scenarios where a MIPS eligible clinician does not receive a quality performance category percent score because there are not sufficient quality measures applicable and available to the clinician or the clinician is facing extreme and uncontrollable circumstances, we propose to redistribute the weight of the cost performance category equally to the remaining performance categories that are not reweighted.

In the rare event a MIPS eligible clinician is not scored on at least one measure in the quality performance category because there are not sufficient measures applicable and available or the clinician is facing extreme and uncontrollable circumstances, we propose for the 2020 MIPS payment year to continue our policy from the transition year and redistribute the 60 percent weight of the quality performance category so that the performance category weights are 50

percent for the advancing care information performance category and 50 percent for the improvement activities performance category (assuming these performance categories do not qualify for reweighting). While clinicians have more experience reporting advancing care information measures, we believe equal weighting to both the improvement activities and advancing care information is appropriate for simplicity. Additionally, in the absence of quality measures, we believe increasing the relative weight of the improvement activities performance category is appropriate because both improvement activities and advancing care information have elements of quality and care improvement which are important to emphasize. Should the cost performance category have available and applicable measures and the cost performance category weight is not zero, but either the improvement activities or advancing care information performance category is reweighted to zero percent, then we would redistribute the weight of the quality performance category to the remaining performance category that is not weighted at zero percent. We would not redistribute the weight to the cost performance category.

We believe that all MIPS eligible clinicians will have sufficient improvement activities applicable and available. It is possible that a MIPS eligible clinician might face extreme and uncontrollable circumstances that render the improvement activities not applicable or available to the clinician; however, in that scenario, we believe it is likely that the measures specified for the other performance categories also would not be applicable or available to the clinician based on the circumstances. In the rare event that the improvement activities performance category would qualify for reweighting based on extreme and uncontrollable circumstances, and the other performance categories would not also qualify for reweighting, we propose to redistribute the improvement activities performance category weight to the quality performance category consistent with the redistribution policies for the cost and advancing care information performance categories. Should the cost performance category have available and applicable measures and the cost performance category weight is not finalized at zero percent, and the quality performance category is reweighted to zero percent, then we would redistribute the weight of the improvement activities performance category to the advancing care information performance category.

Table 38 summarizes the potential reweighting scenarios based on our proposals for the 2020 MIPS payment year should the cost performance category be weighted at zero percent.

TABLE 38—PROPOSED PERFORMANCE CATEGORY REDISTRIBUTION POLICIES FOR THE 2020 MIPS PAYMENT YEAR IF THE COST PERFORMANCE CATEGORY WEIGHT IS ZERO PERCENT

Performance category	Weighting for the 2020 MIPS payment year (%)	Reweight scenario if no advancing care information performance category score (%)	Reweight scenario if no quality performance category percent score	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Advancing Care Information	25	0	50	25

In response to our final policy to redistribute the advancing care information performance category weight solely to the quality performance category in the CY 2017 Quality Payment Program final rule (81 FR 77327), we received some comments expressing concern that this would place undue emphasis on the quality performance category. Commenters expressed the belief that this policy would particularly affect non-patient facing MIPS eligible clinicians who have limited available measures, and would limit the ability to fairly compare different specialties that are reweighted differently. One reason for the discrepancy is that MIPS eligible clinicians that submit data to the advancing care information performance category can readily achieve a base score of 50 percent if they meet the requirements for the base score measures, whereas the quality performance category does not start at the same base. Commenters also expressed the belief that specialties with few quality measures available to them will be unfairly impacted by this reweighting policy, by putting a disproportionate weight on just a few quality measures. Commenters suggested we redistribute the weight of the advancing care information performance category to the improvement activities performance category because the improvement activities performance category allows for the most flexibility. One commenter recommended redistributing the weight of the advancing care information performance category to both the quality and improvement activities performance categories.

We continue to have concerns about increasing the weight of the improvement activities performance category, given that this performance category is based on attestation only and is not connected to a predecessor CMS program like the other MIPS performance categories. However, based on the comments we received, we considered an alternative approach for the 2020 MIPS payment year to redistribute the weight of the advancing care information performance category to the quality and improvement activities performance categories, to minimize the impact of the quality performance category on the final score. For this approach, we would redistribute 15 percent to the quality performance category (60 percent + 15 percent = 75 percent) and 10 percent to the improvement activities performance category (15 percent + 10 percent = 25 percent). We considered redistributing the weight of the advancing care information performance category equally to the quality and improvement activities performance categories. However, for simplicity, we wanted to redistribute the weights in increments of 5 points. Because MIPS eligible clinicians have more experience reporting quality measures and because these measures are more mature, under

this alternative option, we would redistribute slightly more to the quality performance category (15 percent vs. 10 percent). Should the cost performance category have available and applicable measures and the cost performance category weight is not finalized at zero percent and the quality performance category is reweighted to zero percent, then we would redistribute the weight of the advancing care information performance category to the improvement activities performance category. This alternative approach, assuming the cost performance category weight is zero percent is detailed in Table 39.

TABLE 39—ALTERNATIVE OPTION FOR REWEIGHTING THE ADVANCING CARE INFORMATION PERFORMANCE CATEGORY FOR THE 2020 MIPS PAYMENT YEAR IF THE COST PERFORMANCE CATEGORY WEIGHT IS ZERO PERCENT

Performance category	Weighting for the 2020 MIPS payment year (%)	Reweight scenario if no advancing care information performance category score (%)
Quality	60	75
Cost	0	0
Improvement Activities	15	25
Advancing Care Information	25	0

We invite comments on our proposal for weighting the performance categories for the 2020 MIPS payment year and our alternative option for reweighting the advancing care information performance category.

8. MIPS Payment Adjustments

a. Payment Adjustment Identifier and Final Score Used in Payment Adjustment Calculation

(1) Payment Adjustment Identifier

For purposes of applying the MIPS payment adjustment under section 1848(q)(6)(E) of the Act, we finalized a policy in the CY 2017 Quality Payment Program final rule to use a single identifier, TIN/NPI, for all MIPS eligible clinicians, regardless of whether the TIN/NPI was measured as an individual, group or APM Entity group (81 FR 77329 through 77330). In other words, a TIN/NPI may receive a final score based on individual, group, or APM Entity group performance, but the MIPS payment adjustment would be applied at the TIN/NPI level.

We are not proposing any changes to the MIPS payment adjustment identifier.

(2) Final Score Used in Payment Adjustment Calculation

In CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332), we finalized a policy to use a TIN/NPI's historical performance from the performance period associated with the MIPS payment adjustment. We also proposed the following policies, and, although we received public comments on them and responded to those comments, we inadvertently failed to state that we were finalizing these policies, although it was our intention to do so. Thus, we clarify that the following final policies apply beginning with the transition year. For groups submitting data using the TIN identifier, we will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period. For individual MIPS eligible clinicians submitting data using TIN/NPI, we will use the final score associated with the TIN/NPI that is used during the performance period. For eligible clinicians in MIPS APMs, we will assign the APM Entity group's final score to all the APM Entity Participant Identifiers that are associated with the APM Entity. For eligible clinicians that participate in APMs for which the APM scoring standard does not apply, we will assign a final score using either the individual or group data submission assignments.

In the case where a MIPS eligible clinician starts working in a new practice or otherwise establishes a new TIN that did not exist during the performance period, there would be no corresponding historical performance information or final score for the new TIN/NPI. In cases where there is no final score associated with a TIN/NPI from the performance period, we will use the NPI's performance for the TIN(s) the NPI was billing under during the performance period. If the MIPS eligible clinician has only one final score associated with the NPI from the performance period, then we will use that final score. In the event that an NPI bills under multiple TINs in the performance period and bills under a new TIN in the MIPS payment year, we finalized a policy of taking the highest final score associated with that NPI in the performance period (81 FR 77332).

In some cases, a TIN/NPI could have more than one final score associated with it from the performance period, if the MIPS eligible clinician submitted duplicative data sets. In this situation, the MIPS eligible clinician has not changed practices; rather, for example, a MIPS eligible clinician has a final score for an APM Entity and a final score for a group TIN. If a MIPS eligible clinician has multiple final scores, the following hierarchy will apply. If a MIPS eligible clinician is a participant in MIPS APM, then the APM Entity final score would be used instead of any other final score. If a MIPS eligible clinician has more than one APM Entity final score, we will apply the highest APM Entity final score to the MIPS eligible clinician. If a MIPS eligible clinician reports as a group and as an individual and not as an APM Entity, we will calculate a final score for the group and individual identifier and use the highest final score for the TIN/NPI (81 FR 77332).

For a further description of our policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332).

In addition to the above policies from the CY 2017 Quality Payment Program final rule, beginning with the 2020 MIPS payment year, we are proposing to modify the policies to address the addition of virtual groups. Section 1848(q)(5)(I)(i) of the Act provides that MIPS eligible clinicians electing to be a virtual group must: (1) Have their performance assessed for the quality and cost performance categories in a manner that applies the combined performance of all the MIPS eligible clinicians in the virtual group to each MIPS eligible clinician in the virtual group for the applicable performance period; and (2) be scored for the quality

and cost performance categories based on such assessment. Therefore, when identifying a final score for payment adjustments, we must prioritize a virtual group final score over other final scores such as individual and group scores. Because we also wish to encourage movement towards APMs, we will prioritize using the APM Entity final score over any other score for a TIN/NPI, including a TIN/NPI that is in a virtual group. If a TIN/NPI is in both a virtual group and a MIPS APM, we propose to use the waiver authority for Innovation Center models under section 1115A(d)(1) of the Act and the Shared Savings Program waiver authority under section 1899(f) of the Act to waive section 1848(q)(5)(I)(i)(I) and (II) of the Act. As discussed in section II.C.4.h. of this proposed rule, the use of waiver authority is to avoid creating competing incentives between MIPS and the APM. We want MIPS eligible clinicians to focus on the requirements of the APM to ensure that the models produce valid results that are not confounded by the incentives created by MIPS.

We also propose to modify our hierarchy to state that if a MIPS eligible clinician is not in an APM Entity and is in a virtual group, the MIPS eligible clinician would receive the virtual group final score over any other final score. Our policies remain unchanged for TIN/NPIs who are not in an APM Entity or virtual group.

We invite public comment on our proposals.

Table 40 illustrates the previously finalized and newly proposed policies for determining which final score to use when more than one final score is associated with a TIN/NPI.

TABLE 40—HIERARCHY FOR FINAL SCORE WHEN MORE THAN ONE FINAL SCORE IS ASSOCIATED WITH A TIN/NPI

Example	Final score used to determine payment adjustments
TIN/NPI has more than one APM Entity final score	The highest of the APM Entity final scores.
TIN/NPI has an APM Entity final score that is not a virtual group score and also has a group final score.	APM Entity final score.
TIN/NPI has an APM Entity final score and also has a virtual group score.	APM Entity final score.
TIN/NPI has a virtual group score and an individual final score	Virtual group score.
TIN/NPI has a group final score and an individual final score, but no APM Entity final score and is not in a virtual group.	The highest of the group or individual final score.

Table 41 illustrates the previously finalized policies that apply if there is no final score associated with a TIN/NPI from the performance period, such as when a MIPS eligible clinician starts working in a new practice or otherwise establishes a new TIN.

TABLE 41—NO FINAL SCORE ASSOCIATED WITH A TIN/NPI

MIPS eligible clinician (NPI 1)	Performance period final score	TIN/NPI billing in MIPS payment year (yes/no)	Final score used to determine payment adjustments
TIN A/NPI 1	90	Yes (NPI 1 is still billing under TIN A in the MIPS payment year).	90 (Final score for TIN A/NPI 1 from the performance period).
TIN B/NPI 1	70	No (NPI 1 has left TIN B and no longer bills under TIN B in the MIPS payment year).	n/a (no claims are billed under TIN B/NPI 1).
TIN C/NPI 1	n/a (NPI 1 was not part of TIN C during the performance period).	Yes (NPI 1 has joined TIN C and is billing under TIN C in the MIPS payment year).	90 (No final score for TIN C/NPI 1, so use the highest final score associated with NPI 1 from the performance period).

b. MIPS Payment Adjustment Factors

For a description of the statutory background and further description of our policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77332 through 77333).

We are not proposing any changes to these policies.

c. Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of the MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. Section 1848(q)(6)(D)(iii) of the Act outlines a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. We codified the term performance threshold at § 414.1305 as the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the MIPS payment adjustment factors. We codified at § 414.1405(b) that a performance threshold will be specified for each MIPS payment year. We refer readers to the CY 2017 Quality Payment Program final rule for further discussion

of the performance threshold (81 FR 77333 through 77338). In accordance with the special rule set forth in section 1848(q)(6)(D)(iii) of the Act, we finalized a performance threshold of 3 points for the transition year (81 FR 77334 through 77338).

Our goal was to encourage participation and provide an opportunity for MIPS eligible clinicians to become familiar with the MIPS Program. We determined that it would have been inappropriate to set a performance threshold that would result in downward adjustments to payments for many clinicians who may not have had time to prepare adequately to succeed under MIPS. By providing a pathway for many clinicians to succeed under MIPS, we believed that we would encourage early participation in the program, which may enable more robust and thorough engagement with the program over time. We set the performance threshold at a low number to provide MIPS eligible clinicians an opportunity to achieve a minimum level of success under the program, while gaining experience with reporting on the measures and activities and becoming familiar with other program policies and requirements. We believed if we set the threshold too high, using a new formula that is unfamiliar and confusing to clinicians, many could be discouraged from participating in the first year of the program, which may lead to lower participation rates in future years. Additionally, we believed this flexibility is particularly important to reduce the burden for MIPS eligible clinicians in small or solo practices. We believed that active participation of MIPS eligible clinicians in MIPS will improve the overall quality, cost, and care coordination of services provided to Medicare beneficiaries. In accordance with section 1848(q)(6)(D)(iii) of the Act, we took into account available data regarding performance on measures and activities, as well as other factors we determined appropriate. We refer readers to 81 FR 77333 through 77338 for details on our analysis. We also stated our intent to increase the performance threshold in the 2020 MIPS payment year, and that, beginning in the 2021 MIPS payment year, we will use the mean or median final score from a prior period as required by section 1848(q)(6)(D)(i) of the Act (81 FR 77338).

For the 2020 MIPS payment year, we again want to use the flexibility provided in section 1848(q)(6)(D)(iii) to help transition MIPS eligible clinicians to the 2021 MIPS payment year, when the performance threshold will be the mean or median of the final scores for all MIPS eligible clinicians from a prior period. We want to encourage continued participation and the collection of meaningful data by MIPS eligible clinicians. A higher performance threshold would help MIPS eligible clinicians strive to achieve more complete reporting and better performance and prepare MIPS eligible clinicians for the 2021 MIPS payment year. However, a performance threshold set too high could also create a performance barrier, particularly for MIPS eligible clinicians who did not previously participate in PQRS or the EHR Incentive Programs. We have heard from stakeholders requesting that we continue a low performance threshold and from stakeholders requesting that we ramp up the performance threshold to help MIPS eligible clinicians prepare for the 2021 MIPS payment year and to meaningfully incentivize higher performance. Given our desire to provide a meaningful ramp between the transition year's 3-point performance threshold and the 2021 MIPS payment year performance threshold using the mean or median of the final scores for all MIPS eligible clinicians for a prior period, we are proposing to set the performance threshold at 15 points for the 2020 MIPS payment year.

We propose a performance threshold of 15 points because it represents a meaningful increase in performance threshold, compared to 3 points in the transition year, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold. For example, submitting the maximum number of improvement activities could qualify for a score for 15 points (40 out 40 possible points for the improvement activity which is worth 15 percent of the final score). The performance threshold could also be met by full participation in the quality performance category: By submitting all required measures with the necessary data completeness, MIPS eligible clinicians would earn at least a quality performance category percent score of 30 percent (which is 3 measure achievement points out of 10 measure points for each required measure).

If the quality performance category is weighted at 60 percent, then the quality performance category would be 30 percent $\times$ 60 percent $\times$ 100 which equals 18 points toward the final score and exceeds the performance threshold. Finally, a MIPS eligible clinician could achieve a final score of 15 points through an advancing care information performance category score of 60 percent or higher (60 percent advancing care information performance category score $\times$ 25 percent for the advancing care information performance category weight $\times$ 100 equals 15 points towards the final score). We refer readers to section II.C.8.g.(2) of this proposed rule for complete examples of how MIPS eligible clinician could exceed the performance threshold. We believe the proposed performance threshold would mitigate concerns from MIPS eligible clinicians about participating in the program for the second year. However, we remain concerned that moving from a performance threshold of 15 points for the 2020 MIPS payment year to a performance threshold of the mean or median of the final scores for all MIPS eligible clinicians for a prior period for the 2021 MIPS payment year may be a steep jump.

By the 2021 MIPS payment year, MIPS eligible clinicians would likely need to submit most of the required information and perform well on the measures and activities to receive a positive MIPS payment adjustment. Therefore, we also seek comment on setting the performance threshold either lower or higher than the proposed 15 points for the 2020 MIPS payment year. A performance threshold lower than the proposed 15 points for the 2020 MIPS payment year presents the potential for a significant increase in the final score a MIPS eligible clinician must earn to meet the performance threshold in the 2021 MIPS payment year, as well as providing for a potentially smaller total amount of negative MIPS payment adjustments upon which the total amount of the positive MIPS payment adjustments would depend due to the budget neutrality requirement under section 1848(q)(6)(F)(ii) of the Act. A performance threshold higher than the proposed 15 points would increase the final score required to receive a neutral MIPS payment adjustment, which may be particularly challenging for small practices, even with the proposed addition of the small practice bonus. A higher performance threshold would also allow for potentially higher positive MIPS payment adjustments for those who exceed the performance threshold.

We considered an alternative of setting a performance threshold of 6 points, which could be met by submitting two quality measures with required data completeness or one high-weighted improvement activity. While this lower performance threshold may provide a sharp increase to the required performance threshold in MIPS payment year 2021 (the mean or median of the final scores for all MIPS eligible clinicians for a prior period), it would continue to reward clinicians for participation in MIPS as they transition into the program.

We also considered an alternative of setting the performance threshold at 33 points, which would require full participation both in improvement activities and in the quality performance category (either for a small group or for a large group that meets data completeness standards) to meet the performance threshold. Such a threshold would make the step to the required mean or median performance threshold in MIPS payment year 2021 less steep, but could present further challenges to clinicians who have not previously participated in legacy quality reporting programs.

As required by section 1848(q)(6)(D)(iii) of the Act, for the purposes of determining the performance threshold, we considered data available for performance on measures and activities that may be used under the MIPS performance categories. Specifically, we updated our scoring model using 2019 MIPS payment year eligibility data from the initial 12-month period to identify potential MIPS eligible clinicians who are physicians (doctors of medicine, doctors of osteopathy, chiropractors, dentists, optometrists, and podiatrists), nurse practitioners, physician assistants, certified registered nurse anesthetists, and clinical nurse specialists, and who exceeded the low-volume threshold. We estimated newly enrolled Medicare clinicians who would be excluded from MIPS by using clinicians (identified by NPI) that have Part B charges in the eligibility file, but no Part B charges in 2015. To exclude QPs from our scoring model, we used a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. We assumed that all partial QPs would participate in MIPS and included them in our scoring model.

We used 2014 and 2015 PQRS and 2015 VM data to estimate scores for the quality performance category, using the published benchmarks for the 2017 MIPS performance period. We used 2015 and 2016 Medicare and Medicaid EHR Incentive files to estimate advancing care information performance category scores. We also modeled an improvement activities performance category score using assumptions based on prior PQRS and EHR Incentive Program participation. We did not model any cost measures as we proposed in section II.C.6.d.(2) of this proposed rule to weight the cost performance category at zero percent. We refer readers to the regulatory impact analysis in section V.C. of this proposed rule for a detailed description of our scoring model and data sources.

Using 2015 PQRS data, we determined which of these MIPS eligible clinicians participated in PQRS and estimated participation rates for the MIPS quality performance category based on PQRS participation, which is the performance category that accounts for the largest share (a minimum of 60 percent) of the 2020 MIPS payment year final score. We noted that 92.4 percent of the estimated MIPS eligible clinicians submitted data to PQRS, but the participation rate was lower for MIPS eligible clinicians in small practices at 69.7 percent. While we believe many of the policies in this proposed rule and the technical assistance for small practices would help increase participation, we believe it is important to keep the performance threshold low so that these small practices can learn to participate and perform well in MIPS for future years without excessive financial risk.

We invite public comments on the proposal to set the performance threshold at 15 points, and also seek comment on setting the performance threshold at the alternative of 6 points or at 33 points for the 2020 MIPS payment year.

We also seek public comments on principles and considerations for setting the performance threshold beginning with the 2021 MIPS payment year, which will be the mean or median of the final scores for all MIPS eligible clinicians from a prior period.

d. Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under paragraph (C). For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act.

We codified at § 414.1305 the definition of additional performance threshold as the numerical threshold for a MIPS payment year against which the final scores of MIPS eligible clinicians are compared to determine the additional MIPS payment adjustment factors for exceptional performance. We also codified at § 414.1405(d) that an additional performance threshold will be specified for each of the MIPS payment years 2019 through 2024. We refer readers to the CY 2017 Quality Payment Program final rule for further discussion of the additional performance threshold (81 FR 77338 through 77339).

Based on the special rule for the initial 2 years of MIPS in section 1848(q)(6)(D)(iii) of the Act, for the transition year, we decoupled the additional performance threshold from the performance threshold and established the additional performance threshold at 70 points. We selected a 70-point numerical value for the additional performance threshold, in part, because it would require a MIPS eligible clinician to submit data for and perform well on more than one performance category (except in the event the advancing care information performance category is reweighted to zero percent and the weight is redistributed to the quality performance category making the quality performance category worth 85 percent of the final score). Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500,000,000 available for the year under section 1848(q)(6)(F)(iv) of the Act. We believed these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. We took into account the data available and the modeling described in section II.E.7.c.(1) of the CY 2017 Quality Payment Program final rule in selecting the additional performance threshold for the transition year (81 FR 77338 through 77339).

As we discussed in section II.C.8.c. of this proposed rule, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to establish the performance threshold at 15 points for 2020 MIPS payment year. We are proposing to again decouple the additional performance threshold from the performance threshold. Because we do not have actual MIPS final scores for a prior performance period, if we do not decouple the additional performance threshold from the performance threshold, then we would have to set the additional performance threshold at

the 25th percentile of possible final scores above the performance threshold. With a performance threshold set at 15 points, the range of total possible points above the performance threshold is 16 to 100 points. The 25th percentile of that range is 36.25 points, which is barely more than one third of the possible 100 points in the MIPS final score. We do not believe it would be appropriate to lower the additional performance threshold to 36.25 points, as we do not believe a final score of 36.25 points demonstrates exceptional performance by a MIPS eligible clinician. We believe these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to set the additional performance threshold at 70 points for the 2020 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold.

We took into account the data available and the modeling described in section II.C.8.c. of this proposed rule to estimate final scores for the 2020 MIPS payment year. We believe 70 points is appropriate because it requires a MIPS eligible clinician to submit data for and perform well on more than one performance category (except in the event the advancing care information measures are not applicable and available to a MIPS eligible clinician). Generally, a MIPS eligible clinician could receive a maximum score of 60 points for the quality performance category, which is below the 70-point additional performance threshold. In addition, 70 points is at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. For example, if a MIPS eligible clinician gets a perfect score for the improvement activities and advancing care information performance categories, but does not submit quality measures data, then the MIPS eligible clinician would only receive 40 points (0 points for quality + 15 points for improvement activities + 25 points for advancing care information), which is below the additional performance threshold. We believe the additional performance threshold at 70 points maintains the incentive for excellent performance while keeping the focus on quality performance. Finally, we believe keeping the additional performance threshold at 70 points maintains consistency with the 2019 MIPS payment year which helps to simplify the overall MIPS framework.

We invite public comment on these proposals. We also seek feedback on whether we should raise the additional performance threshold to a higher number which would in many instances require the use of an EHR for those to whom the advancing care information performance category requirements would apply. In addition, a higher additional performance threshold would incentivize better performance and would also allow MIPS eligible clinicians to receive a higher additional MIPS payment adjustment.

We also seek public comment on which method we should use to compute the additional performance threshold beginning with the 2021 MIPS payment year. Section 1848(q)(6)(D)(ii) of the Act requires the additional performance threshold to be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold for the year, or the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act. For example, should we use the lower of the two options, which would result in more MIPS eligible clinicians receiving an additional MIPS payment adjustment for exceptional performance? Or should we use the higher of the options, which would restrict the additional MIPS payment adjustment for exceptional performance to those with the higher final scores? Since a fixed amount is available for a year under section 1848(q)(6)(F)(iv) of the Act to fund the additional MIPS payment adjustments, the more clinicians that receive an additional MIPS payment adjustment, the lower the average clinician's additional MIPS payment adjustment will be.

e. Scaling/Budget Neutrality

We codified at § 414.1405(b)(3) that a scaling factor not to exceed 3.0 may be applied to positive MIPS payment adjustment factors to ensure budget neutrality such that the estimated increase in aggregate allowed charges resulting from the application of the positive MIPS payment adjustment factors for the MIPS payment year equals the estimated decrease in aggregate allowed charges resulting from the application of negative MIPS payment adjustment factors for the MIPS payment year. We refer readers to the CY 2017 Quality Payment Program final rule for further discussion of budget neutrality (81 FR 77339).

We are not proposing any changes to the scaling and budget neutrality requirements as they are applied to MIPS payment adjustment factors in this proposed rule.

f. Additional Adjustment Factors

We refer readers to the CY 2017 Quality Payment Program final rule for further discussion of the additional MIPS payment adjustment factor (81 FR 77339 through 77340). We are not proposing any changes to determine the additional MIPS payment adjustment factors.

g. Application of the MIPS Payment Adjustment Factors

(1) Application to the Medicare Paid Amount

Section 1848(q)(6)(E) of the Act provides that for items and services furnished by a MIPS eligible clinician during a year (beginning with 2019), the amount otherwise paid under Part B for such items and services and MIPS eligible clinician for such year, shall be multiplied by 1 plus the sum of the MIPS payment adjustment factor determined under section 1848(q)(6)(A) of the Act divided by 100, and as applicable, the additional MIPS payment adjustment factor determined under section 1848(q)(6)(C) of the Act divided by 100.

We codified at § 414.1405(e) the application of the MIPS payment adjustment factors. For each MIPS payment year, the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor, are applied to Medicare Part B payments for items and services furnished by the MIPS eligible clinician during the year.

We are proposing to apply the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year. This proposal is consistent with the approach taken for the value-based payment modifier (77 FR 69308 through 69310) and would mean that beneficiary cost-sharing and coinsurance amounts would not be affected by the application of the MIPS payment adjustment factor and the additional MIPS payment adjustment factor. The MIPS payment adjustment applies only to the amount otherwise paid under Part B for items and services furnished by a MIPS eligible clinician during a year. Please refer to the CY 2017 Quality Payment Program final rule at 81 FR 77340 and section II.C.3.c.

of this proposed rule for further discussion and our proposals regarding which Part B covered items and services would be subject to the MIPS payment adjustment.

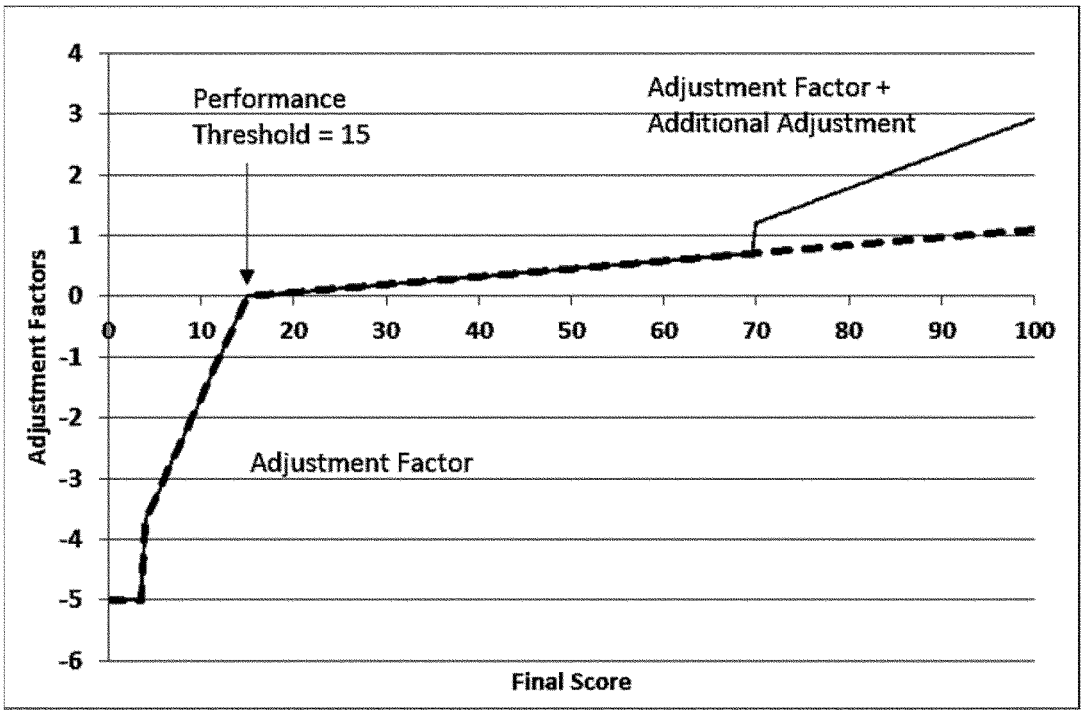
(2) Example of Adjustment Factors

Figure A provides an example of how various final scores would be converted to an adjustment factor, and potentially an additional adjustment factor, using the statutory formula and based on proposed policies. In Figure A, the performance threshold is 15 points. The applicable percentage is 5 percent for 2020. The adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest negative applicable percentage (negative 5 percent for the 2020 MIPS payment year), and 100 being the highest positive applicable percentage. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 3.75 points based on the proposed performance threshold for the 2020 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 5 percent for the 2020 MIPS payment year). Second, the linear sliding scale line for the positive MIPS adjustment factor is adjusted by the scaling factor (as discussed in section II.C.8.e. of this proposed rule). If the scaling factor is greater than zero and less than or equal to 1.0, then the adjustment factor for a final score of 100 would be less than or equal to 5 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the adjustment factor for a final score of 100 would be higher than 5 percent. Only those MIPS eligible clinicians with a final score equal to 15 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because our proposed policies have set the performance threshold at 15 points, we anticipate that the scaling factor would be less than 1.0 and the payment adjustment for MIPS eligible clinicians with a final score of 100 points would be less than 5 percent.

Figure A of this proposed rule illustrates an example slope. In this example, the scaling factor for the adjustment factor is 0.22, which is much lower than 1.0. In this example, MIPS eligible clinicians with a final score equal to 100 would have an adjustment factor of 1.10 percent (5 percent $\times$ 0.22).

The additional performance threshold is 70 points. An additional adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent times a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional adjustment factors is equal to $500,000,000. In Figure A of this proposed rule, the example scaling factor for the additional adjustment factor is 0.183. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional adjustment factor of 1.83 percent (10 percent $\times$ 0.183). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0110 + 0.0183 = 1.0293, for a total positive MIPS payment adjustment of 2.93 percent.

FIGURE A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Proposed Performance Threshold and Additional Performance Threshold for the 2020 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 5 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor.

The final MIPS payment adjustments would be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would have negative MIPS payment adjustments and relatively fewer MIPS eligible clinicians receive positive MIPS payment adjustments.

Table 42 illustrates the changes in payment adjustments from the transition year to the 2020 MIPS payment year based on the proposals in this proposed rule as well as the statutorily-required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 42—ILLUSTRATION OF POINT SYSTEM AND ASSOCIATED ADJUSTMENTS COMPARISON BETWEEN TRANSITION YEAR AND THE 2020 MIPS PAYMENT YEAR

Transition year		2020 MIPS payment year	
Final score points	MIPS adjustment	Final score points	MIPS adjustment
0.0–0.75	Negative 4 percent	0.0–3.75	Negative 5 percent.
0.76–2.99	Negative MIPS payment adjustment greater than negative 4 percent and less than 0 percent on a linear sliding scale.	3.76–14.99	Negative MIPS payment adjustment greater than negative 5 percent and less than 0 percent on a linear sliding scale.
3.00	0 percent adjustment	15.00	0 percent adjustment.
3.01–69.99	Positive MIPS payment adjustment greater than 0 percent on a linear sliding scale multiplied by a scaling factor to preserve budget neutrality.	15.01–69.99	Positive MIPS payment adjustment greater than 0 percent on a linear sliding scale multiplied by a scaling factor to preserve budget neutrality.
	The linear sliding scale ranges from greater than 0 to 4 percent for scores from 3.01 to 100.00.		The linear sliding scale ranges from greater than 0 to 5 percent for scores from 15.01 to 100.00.

TABLE 42—ILLUSTRATION OF POINT SYSTEM AND ASSOCIATED ADJUSTMENTS COMPARISON BETWEEN TRANSITION YEAR AND THE 2020 MIPS PAYMENT YEAR—Continued

Transition year		2020 MIPS payment year	
Final score points	MIPS adjustment	Final score points	MIPS adjustment
70.00–100	Positive MIPS payment adjustment on a linear sliding scale multiplied by a scaling factor to preserve budget neutrality AND additional MIPS payment adjustment for exceptional performance. (Additional MIPS payment adjustment starting at 0.5 percent and increasing on a linear sliding scale to 10 percent multiplied by a scaling factor.) The linear sliding scale ranges from greater than 0 to 4 percent for scores from 3.01 to 100.00.	70.00–100	Positive MIPS payment adjustment on a linear sliding scale multiplied by a scaling factor to preserve budget neutrality AND additional MIPS payment adjustment for exceptional performance. (Additional MIPS payment adjustment starting at 0.5 percent and increasing on a linear sliding scale to 10 percent multiplied by a scaling factor.) The linear sliding scale ranges from greater than 0 to 5 percent for scores from 15.01 to 100.00.

We have provided the following examples for the 2020 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 15 points.

Example 1: MIPS Eligible Clinician in Small Practice Submits 1 Quality Measure and 1 Improvement Activity

In the example illustrated in Table 43, a MIPS eligible clinician in a small practice reporting individually meets the performance threshold by reporting one measure one time via claims and one medium-weight improvement activity. The practice does not submit data for the advancing care information performance category, but does submit a significant hardship exception application which is approved; therefore, the weight for the advancing care information performance category is reweighted to the quality performance category due to proposed reweighting policies discussed in section II.C.7.b,(3) of this proposed rule. We also assume the small practice has a cost performance category percent score of 50 percent, although the cost performance category percent score will not contribute to the final score. Finally, we assume the average HCC score for the beneficiaries seen by the MIPS eligible clinician is 1.5.

There are several special scoring rules which affect MIPS eligible clinicians in a small practice:

- 3 measure achievement points for each quality measure even if the measure does not meet data completeness standards. We refer readers to section II.C.7.a.(2)(d) of this proposed rule for discussion of this policy. Therefore, a quality measure submitted one time would receive 3 points. Because the measure is submitted via claims, it does not qualify for the end-to-end electronic reporting bonus, nor would it qualify for the high-priority bonus because it is the only measure submitted. However, because the MIPS eligible clinician does not meet full participation requirements, the MIPS eligible clinician does not qualify for improvement scoring. We refer you to section II.C.7.a.(2)(i)(iii) of this proposed rule for a discussion on full participation requirements. Therefore, the quality performance category is (3 measure achievement points + zero measure bonus points)/60 total available measure points + zero improvement percent score which is 5 percent.
- The advancing care information performance category weight is redistributed to quality so that the quality performance category percent score is worth 85 percent of the final score. We refer you to section II.C.7.b.(3)(d) of this proposed rule for a discussion of this proposed policy.
- MIPS eligible clinicians in small practices qualify for special scoring for improvement activities so a medium weighted activity is worth 20 points out of a total 40 possible points for the improvement activities performance category. We refer you to section II.C.6.e.(5) of this proposed rule for a discussion of this proposed policy.
- MIPS eligible clinicians in small practices qualify for the 5 point small practice bonus which is applied to the final score. We refer you to section II.C.7.b.(1)(c) of this proposed rule for a discussion of this proposed policy.

This MIPS eligible clinician exceeds the performance threshold of 15 points (but does not exceed the additional performance threshold). This score is summarized in Table 43.

TABLE 43—SCORING EXAMPLE 1, MIPS ELIGIBLE CLINICIAN IN A SMALL PRACTICE

Performance category	Performance score	Category weight	Earned points ([B]*[C]*100)
[A]	[B]	[C]	[D]
Quality	5%	85%	4.25
Cost	50%	0%	0
Improvement Activities	20 out of 40 points—50%.	15%	7.5
Advancing Care Information	Missing	0% (reweighted to quality).	0
Subtotal (Before Bonuses)			11.75
Complex Patient Bonus			1.5
Small Practice Bonus			5
Final Score (not to exceed 100)			18.25

Example 2: Group Submission Not in a Small Group

In the example illustrated in Table 44, a MIPS eligible clinician in a medium size practice participating in MIPS as a group meets 75 percent of the quality score and 100 percent for the advancing care information and improvement activities performance categories. There are many paths for a practice to receive a 75 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Both the performance threshold and the additional performance threshold are exceeded. Again, for simplicity, we assume the average HCC score for the group is 1.5. In this example, the group practice does not qualify for any special scoring, yet is able to exceed the additional performance threshold and achieve the additional adjustment factor.

TABLE 44—SCORING EXAMPLE 2, MIPS ELIGIBLE CLINICIAN IN A MEDIUM PRACTICE

Performance category	Performance score	Category weight	Earned points ([B]*[C]*100)
[A]	[B]	[C]	[D]
Quality	75%	60%	45
Cost	50%	0%	0
Improvement Activities	40 out of 40 points—100%.	15%	15
Advancing Care Information	100%	25%	25
Subtotal (Before Bonuses)			85
Complex Patient Bonus			1.5
Small Practice Bonus			0
Final Score (not to exceed 100)			86.5

Example 3: Non-Patient Facing MIPS Eligible Clinician

In the example illustrated in Table 45, an individual MIPS eligible clinician that is non-patient facing and not in a small practice meets 50 percent of the quality score and 50 percent for 1 medium-weighted for improvement activity. Again, there are many paths for a practice to receive a 50 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Because the MIPS eligible clinician is non-patient facing, they qualify for special scoring for improvement activities, they receive 20 points (out of 40 possible points) for the medium weighted activity. Also, this individual did not submit advancing care information measures and qualifies for the automatic reweighting of the advancing care information performance category to quality. The non-patient facing MIPS eligible clinician has an average HCC score of 1.5, but as the MIPS eligible clinician is not in a small practice, the MIPS eligible clinician does not qualify for the small practice bonus.

In this example, the performance threshold is exceeded while the additional performance threshold is not.

TABLE 45—SCORING EXAMPLE 2, NON-PATIENT FACING MIPS ELIGIBLE CLINICIAN

Performance category	Performance score	Category weight	Earned points ([B]*[C]*100)
[A]	[B]	[C]	[D]
Quality	50%	60%	30
Cost	50%	0%	0
Improvement Activities	20 out of 40 points for 1 medium weight activity—50%.	15%	7.5
Advancing Care Information	0%	25%	0
Subtotal (Before Bonuses)			37.5
Complex Patient Bonus			1.5
Small Practice Bonus			0
Final Score (not to exceed 100)			39

We note that these examples are not intended to be exhaustive of the types of participants nor the opportunities for reaching and exceeding the performance threshold.

9. Review and Correction of MIPS Final Score

a. Feedback and Information To Improve Performance

(1) Performance Feedback

As we have stated previously in the CY 2017 Quality Payment Program final rule (81 FR 77345), we will continue to engage in user research with front-line clinicians to ensure we are providing the performance feedback data in a user-friendly format, and that we are including the data most relevant to clinicians. Any suggestions from user research would be considered as we

develop the systems needed for performance feedback, which would occur outside of the rulemaking process.

Over the past year, we have conducted numerous user research sessions to determine what the community most needs in performance feedback. In summary we have found the users want the following:

(1) To know as soon as possible how I am performing based on my submitted data so that I have confidence that I performed the way I thought I would.

(2) To be able to quickly understand how and why my payments will be adjusted so that I can understand how my business will be impacted.

(3) To be able to quickly understand how I can improve my performance so that I can increase my payment in future program years.

(4) To know how I am performing over time so I can improve the care I am providing patients in my practice.

(5) To know how my performance compares to my peers.

Based on that research, we have already begun development of real-time feedback on data submission and scoring where technically feasible (some scoring requires all clinician data be submitted, and therefore, cannot occur until the end of the submission period). By ''real-time'' feedback, we mean instantaneous feedback; for example, when a clinician submits their data via our Web site or a third party submits data via our Application Program Interface (API), they will know immediately if their submission was successful.

We will continue to provide information for stakeholders who wish to participate in user research via our education and communication channels. Suggestions can also be sent via the ''Contact Us'' information on *qpp.cms.gov*. However, we note that suggestions provided through this channel will not be considered comments on this proposed rule. To submit comments on this proposed rule, please see the explanation of how to submit such comments and relevant deadlines explained at the beginning of this proposed rule.

(a) MIPS Eligible Clinicians

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and advancing care information performance categories.

Beginning July 1, 2018, we are proposing to provide performance feedback to MIPS eligible clinicians and groups for the quality and cost performance categories for the 2017 performance period, and if technically feasible, for the improvement activities and advancing care information performance categories. We propose to provide this performance feedback at least annually, and as, technically feasible, we would provide it more frequently, such as quarterly. If we are able to provide it more frequently, we would communicate the expected frequency to our stakeholders via our education and outreach communication channels.

Based on public comments summarized and responded to in the CY 2017 Quality Payment Program final rule (81 FR 77347), we also propose that the measures and activities specified for the CY 2017 performance period (for all four MIPS performance categories), along with the final score, would be included in the performance feedback provided on or about July 1, 2018. We request comment on these proposals.

For cost measures, since we can measure performance using any 12-month period of prior claims data, we request comment on whether it would be helpful to provide more frequent feedback on the cost performance category using rolling 12-month periods or quarterly snapshots of the most recent 12-month period; how frequent that feedback should be; and the format in which we should make it available to clinicians and groups. In addition, as described in sections II.C.6.b. and II.C.6.d. of this proposed rule, we intend to provide cost performance feedback in the fall of 2017 and the summer of 2018 on new episode-based cost measures that are currently under development by CMS. With regard to the format of feedback on cost measures, we are considering utilizing the parts of the Quality and Resource Use Reports (QRURs) that user testing has revealed beneficial while making the overall look and feel usable to clinicians. We request comment whether that format is appropriate or if other formats or revisions to that format should be used to provide performance feedback on cost measures.

(b) MIPS APMs

We are proposing that MIPS eligible clinicians who participate in MIPS APMs would receive performance feedback in 2018 and future years of the Quality Payment Program, as technically feasible. Please refer to section II.C.6.g.(5) of this proposed rule for additional information related to this proposal.

(c) Voluntary Clinician and Group Reporting

As noted in the CY 2017 Quality Payment Program final rule (81 FR 77071), eligible clinicians who are not included in the definition of a MIPS eligible clinician during the first 2 years of MIPS (or any subsequent year) may voluntarily report on measures and activities under MIPS, but will not be subject to the payment adjustment. In the final rule (81 FR 77346), we summarized public comments requesting that eligible clinicians who are not required, but who voluntarily report on measures and activities under MIPS, should receive the same access to performance feedback as MIPS eligible clinicians, and indicated that we would take the comments into consideration in the future development of performance feedback. We propose to furnish performance feedback to eligible clinicians and groups that do not meet the definition of a MIPS eligible clinician but voluntarily report on measures and activities under MIPS. We propose that this would begin with data collected in performance period 2017, and would be available beginning July 1, 2018. Based on user and market research, we believe that making this information available would provide value in numerous ways. First, it would help clinicians who are excluded from MIPS in the 2017 performance period, but who may be considered MIPS eligible clinicians in future years, to prepare for participation in the Quality Payment Program when there are payment consequences associated with participation. Second, it would give all clinicians equal access to the CMS claims and benchmarking data available in performance feedback. And third, it would allow clinicians who may be interested in participating in an APM to make a more informed decision.

We request comments on this proposal.

(2) Mechanisms

Under section 1848(q)(12)(A)(ii) of the Act, the Secretary may use one or more mechanisms to make performance feedback available, which may include use of a web-based portal or other mechanisms determined appropriate by the Secretary. For the quality performance category, described in section 1848(q)(2)(A)(i) of the Act, the feedback shall, to the extent an eligible clinician chooses to participate in a data registry for purposes of MIPS (including registries under sections 1848(k) and (m) of the Act), be provided based on

performance on quality measures reported through the use of such registries. For any other performance category (that is, cost, improvement activities, or advancing care information), the Secretary shall encourage provision of feedback through qualified clinical data registries (QCDRs) as described in section 1848(m)(3)(E) of the Act.

As previously stated in the CY 2017 Quality Payment Program final rule (81 FR 77347 through 77349), we will use a CMS-designated system as the mechanism for making performance feedback available, which we expect will be a web-based application. We expect to use a new and improved format for the next performance feedback, anticipated to be released around July 1, 2018. It will be provided via the Quality Payment Program Web site (*qpp.cms.gov*), and we intend to leverage additional mechanisms, such as health IT vendors, registries, and QCDRs to help disseminate data and information contained in the performance feedback to eligible clinicians, where applicable.

We are also seeking comment on how health IT, either in the form of an EHR or as a supplemental module, could better support the feedback related to participation in the Quality Payment Program and quality improvement in general. Specifically—

- Are there specific health IT functionalities that could contribute significantly to quality improvement?
- Are there specific health IT functionalities that could be part of a certified EHR technology or made available as optional health IT modules in order to support the feedback loop related to Quality Payment Program participation or participation in other HHS reporting programs?
- In what other ways can health IT support clinicians seeking to leverage quality data reports to inform clinical improvement efforts? For example, are there existing or emerging tools or resources that could leverage an API to provide timely feedback on quality improvement activities?
- Are there opportunities to expand existing tracking and reporting for use by clinicians, for example expanding the feedback loop for patient engagement tools to support remote monitoring of patient status and access to education materials?

We welcome public comment on these questions.

We intend to continue to leverage third party intermediaries as a mechanism to provider performance feedback. In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77386) we finalized that at least 4 times per year, qualified registries and QCDRs will provide feedback on all of the MIPS performance categories that the qualified registry or QCDR reports to us (improvement activities, advancing care information, and/or quality performance category). The feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the qualified registry or QCDR reports. The qualified registry or QCDR is only required to provide feedback based on the MIPS eligible clinician's data that is available at the time the performance feedback is generated. In regard to third party intermediaries, we also noted we would look to propose ''real time'' feedback as soon as it is technically feasible.

Per the policies finalized in the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77386), we continue to require qualified registries and QCDRs, as well as encourage other third party intermediaries (such as health IT vendors that submit data to us on behalf of a MIPS eligible clinician or group), to provide performance feedback to individual MIPS eligible clinicians and groups via the third party intermediary with which they are already working. We also understand that performance feedback is valuable to individual clinicians and groups, and seek feedback from third party intermediaries on when ''real-time'' feedback could be provided.

Additionally, we plan to continue to work with third party intermediaries as we continue to develop the mechanisms for performance feedback, to see where we may be able to develop and implement efficiencies for the Quality Payment Program. We are exploring options with an API, which could allow authenticated third party intermediaries to access the same data that we use to provide confidential feedback to the individual clinicians and groups on whose behalf the third party intermediary reports for purposes of MIPS, in accordance with applicable law, including, but not limited to, the HIPAA Privacy and Security Rules. Our goal is to enable individual clinicians and groups to more easily access their feedback via the mechanisms and relationships they already have established. We are seeking comments on this approach as we continue to develop performance feedback mechanisms. We refer readers to section II.C.10. of this proposed rule for additional information on Third Party Data Submission.

(3) Receipt of Information

Section 1848(q)(12)(A)(v) of the Act, states that the Secretary may use the mechanisms established under section 1848(q)(12)(A)(ii) of the Act to receive information from professionals. This allows for expanded use of the feedback mechanism to not only provide feedback on performance to MIPS eligible clinicians, but to also receive information from professionals.

In the CY 2017 Quality Payment Program final rule (81 FR 77350), we discussed that we intended to explore the possibility of adding this feature to the CMS-designated system, such as a portal, in future years under MIPS. Although we are not making any specific proposals at this time, we are again seeking comment on the features that could be developed for the expanded use of the feedback mechanism. This could be a feature where eligible clinicians and groups can send their feedback (for example, if they are experiencing issues accessing their data, technical questions about their data, etc.) to us through the Quality Payment Program Service Center or the Quality Payment Program Web site. We appreciate that eligible clinicians and groups may have questions regarding the Quality Payment Program information contained in their performance feedback. To assist eligible clinicians and groups, we intend to utilize existing resources, such as a helpdesk or offer technical assistance, to help address questions with the goal of linking these resource features to the Quality Payment Program Web site and Service Center.

(4) Additional Information—Type of Information

Section 1848(q)(12)(B)(i) of the Act states that beginning July 1, 2018, the Secretary shall make available to MIPS eligible clinicians information about the items and services for which payment is made under Title 18 that are furnished to individuals who are patients of MIPS eligible clinicians by other suppliers and providers of services. This information may be made available through mechanisms determined appropriate by the Secretary, such as the CMS-designated system that would also provide performance feedback. Section 1848(q)(12)(B)(ii) of the Act specifies that the type of information provided may include the name of such providers, the types of items and services furnished, and the dates that items and services were furnished. Historical data regarding the total, and components of, allowed charges (and

other figures as determined appropriate by the Secretary) may also be provided.

We propose, beginning with the performance feedback provided around July 1, 2018, to make available to MIPS eligible clinicians and eligible clinicians information about the items and services for which payment is made under Title 18 that are furnished to individuals who are patients of MIPS eligible clinicians and eligible clinicians by other suppliers and providers of services. We propose to include as much of the following data elements as technically feasible: The name of such suppliers and providers of services; the types of items and services furnished and received; the dollar amount of services provided and received; and the dates that items and services were furnished. We propose that the additional information would include historical data regarding the total, and components of, allowed charges (and other figures as determined appropriate). We propose that this information be provided on the aggregate level; with the exception of data on items and services, as we could consider providing this data at the patient level, if clinicians find that level of data to be useful, although we note it may contain personally identifiable information and protected health information. We propose the date range for making this information available would be based on what is most helpful to clinicians, such as the most recent data we have available, which as technically feasible would be provided from a 3 to 12-month period. We propose to make this information available via the Quality Payment Program Web site, and as technically feasible, as part of the performance feedback. Finally, because data on items and services furnished is generally kept confidential, we propose that access would be provided only after secure credentials are obtained. We request comment on these proposals.

(5) Performance Feedback Template

As we have previously indicated (81 FR 77352), we intend to do as much as we can of the development of the template for performance feedback by working with the stakeholder community in a transparent manner. We believe this will encourage stakeholder commentary and make sure the result is the best possible format(s) for feedback.

To continue with our collaborative goal of working with the stakeholder community, we seek comment on the structure, format, content (for example, detailed goals, data fields, and elements) that would be useful for MIPS eligible clinicians and groups to include in performance feedback, including the data on items and services furnished, as discussed above. Additionally, we understand the term ''performance feedback'' may not be meaningful to clinicians or groups to clearly denote what this data might imply. Therefore, we seek comment on what to term ''performance feedback.'' User testing to date has provided some considerations for a name in the Quality Payment Program, such as Progress Notes, Reports, Feedback, Performance Feedback, or Performance Reports.

Any suggestions on the template to be used for performance feedback or what to call ''performance feedback'' can be submitted to the Quality Payment Program Web site at *qpp.cms.gov.*

b. Targeted Review

In the CY 2017 Quality Payment Program final rule (81 FR 77546), we finalized at § 414.1385 that MIPS eligible clinicians or groups may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act applicable to such MIPS eligible clinician or group for a year. We note MIPS eligible clinicians who are scored under the APM scoring standard described in section II.C.6.g. of this proposed rule may request this targeted review. Although we are not proposing any changes to the targeted review process, we are providing information on the process that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358).

(1) MIPS eligible clinicians and groups have a 60-day period to submit a request for targeted review, which begins on the day we make available the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor, for the MIPS payment year and ends on September 30 of the year prior to the MIPS payment year or a later date specified by us.

(2) We will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted. Examples under which a MIPS eligible clinician or group may wish to request a targeted review include, but are not limited to:

- The MIPS eligible clinician or group believes that measures or activities submitted to us during the submission period and used in the calculations of the final score and determination of the adjustment factors have calculation errors or data quality issues. These submissions could be with or without the assistance of a third party intermediary; or
- The MIPS eligible clinician or group believes that there are certain errors made by us, such as performance category scores were wrongly assigned to the MIPS eligible clinician or group (for example, the MIPS eligible clinician or group should have been subject to the low-volume threshold exclusion and should not have received a performance category score).

(3) The MIPS eligible clinician or group may include additional information in support of their request for targeted review at the time the request is submitted. If we request additional information from the MIPS eligible clinician or group, it must be provided and received by us within 30 days of the request. Non-responsiveness to the request for additional information may result in the closure of the targeted review request, although the MIPS eligible clinician or group may submit another request for targeted review before the deadline.

(4) Decisions based on the targeted review are final, and there is no further review or appeal.

c. Data Validation and Auditing

In the CY 2017 Quality Payment Program final rule (81 FR 77546 through 77547), we finalized at § 414.1390(a) that we will selectively audit MIPS eligible clinicians and groups on a yearly basis. If a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or group will be required to do the following in accordance with applicable law and timelines we establish:

(1) Comply with data sharing requests, providing all data as requested by us or our designated entity. All data must be shared with us or our designated entity within 45 days of the data sharing request, or an alternate timeframe that is agreed to by us and the MIPS eligible clinician or group. Data will be submitted via email, facsimile, or an electronic method via a secure Web site maintained by us.

(2) Provide substantive, primary source documents as requested. These documents may include: Copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives, and activities. Primary source documentation also may include verification of records for Medicare and non-Medicare beneficiaries where applicable. We are not proposing any changes to the requirements in section § 414.1390(a).

We indicated in the CY 2017 Quality Payment Program final rule that all

MIPS eligible clinicians and groups that submit data to us electronically must attest to the best of their knowledge that the data submitted to us is accurate and complete (81 FR 77362). We also indicated in the final rule that attestation requirements would be part of the submission process (81 FR 77360). We neglected to codify this requirement in regulation text of the CY 2017 Quality Payment Program final rule. Additionally, after further consideration since the final rule, the requirement is more in the nature of a certification, rather than an attestation. Thus, we are proposing to revise § 414.1390 to add a new paragraph (b) that requires all MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS to certify to the best of their knowledge that the data submitted to CMS is true, accurate, and complete. We also propose that the certification by the MIPS eligible clinician or group must accompany the submission.

We also indicated in the CY 2017 Quality Payment Program final rule that if a MIPS eligible clinician or group is found to have submitted inaccurate data for MIPS, we would reopen and revise the determination in accordance with the rules set forth at §§ 405.980 through 405.984 (81 FR 77362). We neglected to codify this policy in regulation text of the CY 2017 Quality Payment Program final rule and further, we did not include § 405.986, which is also an applicable rule in our reopening policy. We also finalized our approach to recoup incorrect payments from the MIPS eligible clinician by the amount of any debts owed to us by the MIPS eligible clinician and likewise, we would recoup any payments from the group by the amount of any debts owed to us by the group. Thus, we are proposing to revise § 414.1390 to add a new paragraph (c) that states we may reopen and revise a MIPS payment determination in accordance with the rules set forth at §§ 405.980 through 405.986.

In the CY 2017 Quality Payment Program, we also indicated that MIPS eligible clinicians and groups should retain copies of medical records, charts, reports and any electronic data utilized for reporting under MIPS for up to 10 years after the conclusion of the performance period (81 FR 77360). We neglected to codify this policy in regulation text of the CY 2017 Quality Payment Program final rule. Thus, we are proposing to revise § 414.1390 to add a new paragraph (d) that states that all MIPS eligible clinicians or groups that submit data and information to CMS for purposes of MIPS must retain such data and information for a period of 10 years from the end the MIPS Performance Period.

Finally, we indicated in the CY 2017 Quality Payment Program final rule, that, in addition to recouping any incorrect payments, we intend to use data validation and audits as an educational opportunity for MIPS eligible clinicians and groups and we note that this process will continue to include education and support for MIPS eligible clinicians and groups selected for an audit.

10. Third Party Data Submission

In developing MIPS, our goal is to develop a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians. Flexible reporting options will provide eligible clinicians with options to accommodate different practices and make measurement meaningful. We believe that allowing eligible clinicians to participate in MIPS through the use of third party intermediaries that will collect or submit data on their behalf, will help us accomplish our goal of implementing a flexible program. We strongly encourage all third party intermediaries to work with their MIPS eligible clinicians to ensure the data submitted are representative of the individual MIPS eligible clinician's or group's overall performance for that measure or activity.

For purposes of this section, we use the term third party to refer to a qualified registry, QCDR, a health IT vendor or other third party that obtains data from a MIPS eligible clinician's Certified Electronic Health Record Technology, or a CMS approved survey vendor. In the CY 2017 Quality Payment Program final rule (81 FR 77363), we finalized at § 414.1400(a)(1) that MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: (1) A qualified registry; (2) a QCDR; (3) a health IT vendor; or (4) a CMS approved survey vendor. Additionally, we finalized at § 414.1400(a)(3) that third party intermediaries must meet all the criteria designated by us as a condition of their qualification or approval to participate in MIPS as a third party intermediary. Lastly, as finalized at § 414.1400(a)(3)(ii), all submitted data must be submitted in the form and manner specified by us.

We are proposing to revise § 414.1400(a)(1) to state that MIPS data may be submitted by third party intermediaries on behalf of an individual MIPS eligible clinician, group, or virtual group. See section II.C.4. of this rule for more information related to virtual groups.

Additionally, we believe it is important that the MIPS data submitted by third party intermediaries is true, accurate, and complete. To that end, we are proposing to add a requirement at § 414.1400(a)(5) stating that all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete. We also propose that this certification occur at the time of the submission and accompany the submission. We solicit comments on this proposal.

As more clinicians participate in value based payment arrangements with multiple payers, we believe third-party intermediaries will play an important role in calculating quality measures, reporting once to all payers, and sharing actionable feedback to clinicians. A robust ecosystem of third-party intermediaries would more reliably calculate measures using data across clinical practices caring for the same patients and reduce burden by streamlining reporting to all payers and offering timely feedback to clinicians that is easier to act on in addressing gaps in care. Third-party intermediaries can also take the burden off clinical practices by integrating various types of health care data, including administrative data from payers, other utilization data, cost data, and clinical data derived from health IT systems, to provide front-line clinicians and others with a comprehensive view of the cost and quality of the care they are delivering.

We are continuing to explore how we can further encourage those third-party intermediaries that provide comprehensive data services to support eligible clinicians participating in both MIPS and APMs. For instance, should we consider implementing additional incentives for eligible clinicians to use a third-party intermediary which has demonstrated substantial participation from additional payers and/or other clinical data sources across practices caring for a cohort of Medicare beneficiaries within a given geographic area? Should these incentives also include expectations that structured, standardized data be shared with third party intermediaries? Should there be additional refinements to the approach to qualifying third party intermediaries which evaluate the degree to which these intermediaries can deliver longitudinal information on a patient to participating clinicians, for example, a

virtual care team of primary and specialty physicians? Should there be a special designation for registries that would convey the availability of longitudinal clinical data for robust measurement and feedback? We seek comment on these and other ideas which can further advance the role of intermediaries and reduce clinician burden by enabling a streamlined reporting and feedback system.

a. Qualified Clinical Data Registries (QCDRs)

In the CY 2017 Quality Payment Program final rule (81 FR 77364), we finalized the definition and capabilities of a QCDR. We are not proposing any changes to the definition or the capabilities of a QCDR in this proposed rule, and refer readers to the CY 2017 Quality Payment Program final rule for a detailed discussion of the definition and capabilities of a QCDR.

(1) Establishment of an Entity Seeking To Qualify as a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77365), we finalized the criteria to establish an entity seeking to qualify as a QCDR. We are not proposing any changes to the criteria in this proposed rule, and refer readers to the CY 2017 Quality Payment Program final rule for the criteria to qualify as a QCDR.

(2) Self-Nomination Period

In the CY 2017 Quality Payment Program final rule (81 FR 77365 through 77366), we finalized the self-nomination period for the 2018 performance period and for future years of the program to be from September 1 of the year prior to the applicable performance period until November 1 of the same year. As an example, the self-nomination period for the 2018 performance period will begin on September 1, 2017, and will end on November 1, 2017. Entities that desire to qualify as a QCDR for the purposes of MIPS for a given performance period will need to self-nominate for that year and provide all information requested by us at the time of self-nomination. Having qualified as a QCDR in a prior year does not automatically qualify the entity to participate in MIPS as a QCDR in subsequent performance periods. Furthermore, prior performance of the QCDR (when applicable) will be taken into consideration in approval of their self-nomination. For example, a QCDR may choose not to continue participation in the program in future years, or the QCDR may be precluded from participation in a future year due to multiple data or submission errors as noted below. Finally, QCDRs may want to update or change the measures or services or performance categories they intend to provide. We believe an annual self-nomination process is the best process to ensure accurate information is conveyed to MIPS eligible clinicians and accurate data is submitted to MIPS.

However, we do understand that some QCDRs have no changes to the measure and/or activity inventory they offer to their clients and intend to participate in the MIPS for many years. Because of this, we are proposing, beginning with the 2019 performance period, a simplified process in which existing QCDRs in good standing may continue their participation in MIPS, by attesting that the QCDR's approved data validation plan, cost, measures, activities, services, and performance categories offered in the previous year's performance period of MIPS have minimal or no changes and will be used for the upcoming performance period. Specifically, existing QCDRs in good standing may attest during the self-nomination period that they have no changes to their approved self-nomination application from the previous year of MIPS. In addition, the existing QCDRs may decide to make minimal changes to their approved self-nomination application from the previous year, which would be submitted by the QCDR for CMS review and approval by the close of the self-nomination period. Minimal changes may include limited changes to their performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. Existing QCDRs in good standing, may also submit for CMS review and approval, substantive changes to measure specifications for existing QCDR measures that were approved the previous year, or submit new QCDR measures for CMS review and approval without having to complete the entire self-nomination application process, which is required to be completed by a new QCDR. By attesting that certain aspects of their approved application from the previous year have not changed, existing QCDRs in good standing would be spending less time completing the entire self-nomination form, as was previously required on a yearly basis. We are proposing such a simplified process to reduce the burden of self-nomination for those existing QCDRs who have previously participated in MIPS, and are in good standing (not on probation or disqualified, as described below) and to allow for sufficient time for us to review data submissions and to make determinations on the standing of the QCDRs. We note that substantive changes to existing QCDR measure specifications or any new QCDR measures would have to be submitted for CMS review and approval by the close of the self-nomination period. This proposed process will allow existing QCDRs in good standing to avoid completing the entire application annually, as is required in the existing process, and in alignment with the existing timeline. We request comments on this proposal. In the development of this proposal, we had reviewed the possibility of offering a multi-year approval, where QCDRs would be approved for a 2-year increment of time. We are concerned that utilizing a multi-year approval process in which QCDRs would be approved for 2 continuous years using the same fixed services they had for the first year, would not provide the QCDR with the flexibility to add or remove services and/or measures or activities based on their QCDR capabilities for the upcoming program year. Furthermore, another concern with a multi-year approval process is the concern for those QCDRs who perform poorly during the first year, and who should be placed on probation or disqualified (as described below). We request comments on this alternative.

We finalized to require other information (described below) of QCDRs at the time of self-nomination. If an entity becomes qualified as a QCDR, they will need to sign a statement confirming this information is correct prior to listing it on their Web site. Once we post the QCDR on our Web site, including the services offered by the QCDR, we will require the QCDR to support these services or measures for its clients as a condition of the entity's qualification as a QCDR for purposes of MIPS. Failure to do so will preclude the QCDR from participation in MIPS in the subsequent year.

For future years, beginning with the 2018 performance period, we are proposing that self-nomination information must be submitted via a web-based tool, and to eliminate the submission method of email. We will provide further information on the web-based tool at *www.qpp.cms.gov*. We request comments on this proposal.

(3) Information Required at the Time of Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367), we finalized the information a QCDR must provide to us at the time of self-nomination. We are proposing to replace the term non-MIPS measures

with QCDR measures for future program years, beginning with the 2018 performance period. We note that although we are proposing a change in the term referring to such measures, we are not proposing any other changes to the information a QCDR must provide to us at the time of self-nomination finalized in the CY 2017 Quality Payment Program final rule. We refer readers to the CY 2017 Quality Payment Program final rule for specific information requirements.

(4) QCDR Criteria for Data Submission

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374), we finalized that a QCDR must perform specific functions to meet the criteria for data submission. While we are not proposing any changes to the criteria for data submission in this proposed rule, we would like to note the following as clarifications to existing criteria. Specifically, a QCDR—

- Must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures. That is, we expect that the QCDR measures, and their data elements (that is, specifications) comprising these measures be listed on the QCDR's Web site unless the measure is a MIPS measure, in which case the specifications will be posted by us. QCDR measure specifications should be provided at a level of detail that is comparable to what is posted by us on the CMS Web site for MIPS quality measures specifications.
- Approved QCDRs may post the MIPS quality measure specifications on their Web site, if they so choose. If the MIPS quality measure specifications are posted by the QCDRs, they must replicate exactly the same as the MIPS quality measure specifications posted on the CMS Web site.
- Enter into and maintain with its participating MIPS eligible clinicians an appropriate Business Associate agreement that complies with the HIPAA Privacy and Security Rules. Ensure that the Business Associate agreement provides for the QCDR's receipt of patient-specific data from an individual MIPS eligible clinician or group, as well as the QCDR's disclosure of quality measure results and numerator and denominator data or patient specific data on Medicare and non-Medicare beneficiaries on behalf of MIPS eligible clinicians and groups.
- Must provide timely feedback at least 4 times a year, on all of the MIPS performance categories that the QCDR will report to us. We refer readers to section II.C.9.a. of this proposed rule for additional information on third party intermediaries and performance feedback.
- For purposes of distributing performance feedback to MIPS eligible clinicians, we encourage QCDRs to assist MIPS eligible clinicians in the update of their email addresses in CMS systems—including PECOS and the Identity and Access System—so that they have access to feedback as it becomes available on *www.qpp.cms.gov* and have documentation from the MIPS eligible clinician authorizing the release of his or her email address.

As noted in the CY 2017 Quality Payment Program final rule (81 FR 77370), we will on a case-by-case basis allow QCDRs and qualified registries to request review and approval for additional MIPS measures throughout the performance period. We would like to explain that this flexibility would only apply for MIPS measures; QCDRs will not be able to request additions of any new QCDR measures throughout the performance period. QCDRs will not be able to retire any measures they are approved for during the performance period. Should a QCDR encounter an issue regarding the safety or change in evidence for a measure during the performance period, they must inform CMS of said issue and indicate whether they will or will not be reporting on the measure, and we will review measure issues on a case-by-case basis. Any measures QCDRs wish to retire would need to be retained until the next annual self-nomination process and applicable performance period.

(5) QCDR Measure Specifications Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), we specified at § 414.1400(f) that the QCDR must provide specific QCDR measures specifications criteria. We generally intend to apply a process similar to the one used for MIPS measures to QCDR measures that have been identified as topped out. We are not proposing any changes to the QCDR measure specifications criteria as finalized in the CY2017 Quality Payment Program final rule. We would like to note that for QCDR quality measures, we encourage alignment with our measures development plan, but will consider all QCDR measures submitted by the QCDR. For MIPS measures, we would also like to note that CMS expects that a QCDR reporting on MIPS measures retain and use the MIPS specifications as they exist for the performance period.

We would like to clarify that we will likely not approve retired measures that were previously in one of CMS's quality programs, such as the Physician Quality Reporting System (PQRS) program, if proposed as QCDR measures. This includes measures that were retired due to being topped out (as defined in section II.C.6.c.(2) of this proposed rule) due to high-performance or measures retired due to a change in the evidence supporting the use of the measure.

We seek comment for future rulemaking, on requiring QCDRs that develop and report on QCDR measures, must fully develop and test (that is, conduct reliability and validity testing) their QCDR measures, by the time of submission of the new measure during the self-nomination process.

Beginning with the 2018 performance period and for future program years, we propose that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. If a QCDR would like report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure that they can use the measure for the performance period. Permission must be granted at the time of self-nomination, so that the QCDR that is using the measure can include the proof of permission for CMS review and approval for the measure to be used in the performance period. The QCDR measure owner (QCDR vendor) would still own and maintain the QCDR measure, but would allow other approved QCDRs to utilize their QCDR measure with proper notification. This proposal will help to harmonize clinically similar measures and limit the use of measures that only slightly differ from another. We invite comments on this proposal.

We would like to clarify from the CY 2017 Quality Payment Program final rule (81 FR 77375) that the QCDR must publicly post the measure specifications no later than 15 calendar days following our approval of these measures specifications for each QCDR measure it intends to submit for MIPS.

We refer readers to the CY 2017 Quality Payment Program final rule for the QCDR measure specifications criteria.

(6) Identifying QCDR Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we finalized the definition and types of QCDR quality measures for purposes of QCDRs submitting data for the MIPS quality performance category. We are not proposing any changes to the criteria on how to identify QCDR quality measures in this proposed rule. We would like to clarify that QCDRs are not limited to reporting on QCDR measures,

and may also report on MIPS measures as indicated above in the QCDR data submission criteria section.

(7) Collaboration of Entities To Become a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77377), we finalized policy on the collaboration of entities to become a QCDR. We are not proposing any changes to this policy in this proposed rule, and would refer readers to the CY 2017 Quality Payment Program final rule for the criteria.

In response to the CY 2017 Quality Payment Program final rule, commenters recommended that we work with QCDRs to determine a more reasonable cycle for self-nomination, measure selection, and reporting because the current process is burdensome. Commenters also recommended that we not disqualify QCDRs that do not have the capability to allow MIPS eligible clinicians to report across all performance categories using only one submission mechanism, and noted that the ability for QCDRs to report their own measures allows MIPS eligible clinicians the ability to implement measures that are more clinically meaningful and up-to-date than those measures that may be available in the MIPS measure set. We would like to note that we are proposing above, a simplified self-nomination and measure selection process available to existing QCDRs that are in good standing, beginning in the third year of the Quality Payment Program. We would also like to explain that QCDRs are not required to report on all performance categories across the MIPS program, and would not be disqualified for not being able to report data across on performance categories only using one mechanism. We thank the commenters for their support with regards to allowing QCDRs to nominate and report on QCDR measures that may be specialty related. We thank the commenters for their feedback and will take their comments into consideration in future rule making.

b. Health IT Vendors That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT)

In the CY 2017 Quality Payment Program final rule 81 FR 77382, we finalized definitions and criteria around health IT vendors that obtain data from MIPS eligible clinicians CEHRT. We note that, for this proposed rule, a health IT vendor that serves as a third party intermediary to collect or submit data on behalf MIPS eligible clinicians may or may not also be a ''health IT developer.'' Under the ONC Health IT Certification Program (Program), (80 FR 62604), a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. The use of ''health IT developer'' is consistent with the use of the term ''health IT'' in place of ''EHR'' or ''EHR technology'' under the Program (see 80 FR 62604; and section II.C.6.f. of this proposed rule). Throughout this proposed rule, we use the term ''health IT vendor'' to refer to entities that support the health IT requirements of a clinician participating in the Quality Payment Program.

We are not proposing any changes to this policy in this proposed rule, and would refer readers to the CY 2017 Quality Payment Program final rule for the criteria. However we seek comment for future rulemaking regarding the potential shift to seeking alternatives which might fully replace the QRDA III format in the Quality Payment Program in future program years.

c. Qualified Registries

In the CY 2017 Quality Payment Program final rule (81 FR 77382 through 77386), we finalized the definition and capability of qualified registries. We are not proposing any changes to the definition or the capabilities of qualified registries in this final rule, and refer readers to the CY 2017 Quality Payment Program final rule for the detailed definition and capabilities of a qualified registry.

(1) Establishment of an Entity Seeking To Qualify as a Registry

In the CY 2017 Quality Payment Program final rule (81 FR 77383), we finalized the requirements for the establishment of an entity seeking to qualify as a registry. We are not proposing any changes to the criteria regarding the establishment of an entity seeking to qualify as a registry criteria in this proposed rule, and refer readers to the final rule for the criteria for establishing an entity seeking to qualify as a registry.

(2) Self-Nomination Period

For the 2018 performance period, and for future years of the program, we finalized at § 414.1400(g) a self-nomination period from September 1 of the year prior to the applicable performance period, until November 1 of the same year. For example, for the 2018 performance period, the self-nomination period would begin on September 1, 2017, and end on November 1, 2017. Entities that desire to qualify as a qualified registry for purposes of MIPS for a given performance period will need to provide all requested information to us at the time of self-nomination and would need to self-nominate for that performance period. Having previously qualified as a qualified registry does not automatically qualify the entity to participate in subsequent MIPS performance periods. Furthermore, prior performance of the qualified registry (when applicable) will be taken into consideration in approval of their self-nomination. For example, a qualified registry may choose not to continue participation in the program in future years, or the qualified registry may be precluded from participation in a future year, due to multiple data or submission errors as noted below. As such, we believe an annual self-nomination process is the best process to ensure accurate information is conveyed to MIPS eligible clinicians and accurate data is submitted to MIPS.

However, we do understand that some qualified registries have no changes to the measures and/or activity inventory they offer to their clients and intend to participate in MIPS for many years. Because of this, we are proposing, beginning with the 2019 performance period, a simplified process in which existing qualified registries in good standing may continue their participation in MIPS by attesting that the qualified registry's approved data validation plan, cost, approved MIPS quality measures, services, and performance categories offered in the previous year's performance period of MIPS have minimal or no changes and will be used for the upcoming performance period. Specifically, existing qualified registries in good standing may attest during the self-nomination period that they have no changes to their approved self-nomination application from the previous year of MIPS. In addition, the existing qualified registry may decide to make minimal changes to their self-nomination application from the previous year, which would be submitted by the qualified registry for CMS review and approval by the close of the self-nomination period. Minimal changes may include limited changes to their performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. By attesting that certain aspects of their approved application from the previous year have not changed, existing qualified registries will be spending less time completing the entire self-nomination form, as was previously required on a yearly basis. We are proposing such a simplified process to reduce the burden of self-

nomination for those existing qualified registries who have previously participated in MIPS, and are in good standing (not on probation or disqualified, as described below) and to allow for sufficient time for us to review data submissions and to make determinations on the standing of qualified registries. This proposed process will allow existing qualified registries in good standing to avoid completing the entire application annually, as is required in the existing process, and in alignment with the existing timeline. We request comments on this proposal. In the development of this proposal, we had reviewed the possibility of offering a multi-year approval, where qualified registries would be approved for a 2-year increment of time. We are concerned that utilizing a multi-year approval process in which qualified registries would be approved for 2 continuous program years using the same fixed services they had for the first year, would not provide the qualified registry with the flexibility to add or remove services and or measures based on their capabilities for the upcoming program year. Furthermore, another concern with a multi-year approval process is the concern for those qualified registries who perform poorly during the first year, who should be placed on probation or disqualified (as described below). We are proposing that this process be conducted on a yearly basis, from September 1 of the year prior to the applicable performance period until November 1 of the same year, starting in 2018, aligning with the annual self-nomination period in order to ensure that only those qualified registries who are in good standing utilize this process. We believe that this annual process will provide qualified registries with the flexibility to make minor changes to their services should they wish to do so. We request comments on this proposal. We also seek comment to potentially allow for qualified registries to utilize a multi-year approval process, in which they would be approved for a continuous 2-year increment since qualified registries can only make minor changes (for example, including a performance category, or a MIPS quality measure, all of which are already considered a part of the MIPS program).

We finalized to require further information of qualified registries at the time of self-nomination. If an entity becomes qualified as a qualified registry, they would need to sign a statement confirming this information is correct prior to us listing their qualifications on their Web site. Once we post the qualified registry on our Web site, including the services offered by the qualified registry, we would require the qualified registry to support these services/measures for its clients as a condition of the entity's qualification as a qualified registry for purposes of MIPS. Failure to do so will preclude the qualified registry from participation in MIPS in the subsequent performance year.

For the 2018 performance period and beyond, we are proposing that self-nomination information must be submitted via a web-based tool, and to eliminate the submission method of email. We will provide further information on the web-based tool at *www.qpp.cms.gov*. We request comments on this proposal.

(3) Information Required at the Time of Self-Nomination

We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77384) that a qualified registry must provide specific information to us at the time of self-nomination. We are not proposing any changes to the information required at the time of self-nomination in this proposed rule, and refer readers to the final rule for specific information requirements.

(4) Qualified Registry Criteria for Data Submission

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the criteria for qualified registry data submission. We are not proposing any changes to the data submission criteria in this proposed rule, and refer readers to the final rule for specific criteria regarding qualified registry data submission. We would like to note two clarifications to the existing criteria:

- Enter into and maintain with its participating MIPS eligible clinicians an appropriate Business Associate agreement that complies with the HIPAA Privacy and Security Rules. Ensure that the Business Associate agreement provides for the Qualified Registry's receipt of patient-specific data from an individual MIPS eligible clinician or group, as well as the Qualified Registry's disclosure of quality measure results and numerator and denominator data or patient specific data on Medicare and non-Medicare beneficiaries on behalf of individual MIPS eligible clinicians and groups.
- We had finalized that timely feedback be provided at least four times a year, on all of the MIPS performance categories that the qualified registry will report to us. We refer readers to section II.C.9.a. of this proposed rule for additional information on third party intermediaries and performance feedback.

We had received comments in response to the CY 2017 Quality Payment Program final rule from commenters who expressed concern that the 3 percent acceptable error rate for qualified registries is too low. Commenters recommended we analyze reporting for the transition year and increase the error rate to 5 percent at the minimum because qualified registries may make a small number of errors given that 2017 is the first year of MIPS and that removing qualified registries due to a low error threshold could hurt clinicians. We thank the commenters for their feedback and will take the comments into consideration in future rulemaking.

As indicated in the CY 2017 Quality Payment Program final rule (81 FR 77370), we will on a case-by-case basis allow qualified registries to request review and approval for additional MIPS measures throughout the performance period. Any new measures that are approved by us will be added to the information related to the qualified registry on the CMS Web site, as technically feasible. We anticipate only being able to update this information on the Web site on a quarterly basis, as technically feasible.

d. CMS-Approved Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the definition, criteria, required forms, and vendor business requirements needed to participate in MIPS as a survey vendor. We refer readers to the CY 2017 Quality Payment Program final rule for specific details on requirements. We have heard from some groups that it would be useful to have a final list of CMS-approved survey vendors to inform their decision on whether or not to participate in the CAHPS for MIPS survey. Therefore, beginning with the 2018 performance period and for future program years, we propose to remove the April 30th survey vendor application deadline because this deadline is within the timeframe of when groups can elect to participate in the CAHPS for MIPS survey. In order to provide a final list of CMS-approved survey vendors earlier in the timeframe during which groups can elect to participate in the CAHPS for MIPS survey, an earlier vendor application deadline would be necessary. This could be accomplished by having a rolling application period, where vendors would be able to submit an application by the end of the first quarter. However, in addition to

submitting a vendor application, vendors must also complete vendor training and submit a Quality Assurance Plan and we need to allow sufficient time for these requirements as well. Therefore, we propose for the Quality Payment Program Year 2 and future years that the vendor application deadline would be January 31st of the applicable performance year or a later date specified by CMS. This proposal would allow us to adjust the application deadline beyond January 31st on a year to year basis, based on program needs. We will notify vendors of the application deadline to become a CMS-approved survey vendor through additional communications and postings. We request comments on this proposal and other alternatives that would allow us to provide a final list of CMS-approved survey vendors early in the timeframe during which groups can elect to participate in the CAHPS for MIPS survey.

e. Probation and Disqualification of a Third Party Intermediary

At § 414.1400(k), we finalized the process for placing third party intermediaries on probation and for disqualifying such entities for failure to meet certain standards established by us (81 FR 77386). Specifically, we proposed that if at any time we determine that a third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) has not met all of the applicable criteria for qualification, we may place the third party intermediary on probation for the current performance period or the following performance period, as applicable.

In addition, we finalized that we require a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring. We finalized that the corrective action plan must be received and accepted by us within 14 days of the CMS notification to the third party intermediary of the deficiencies or probation. Failure to comply with these corrective action plan requirements would lead to disqualification from MIPS for the subsequent performance period.

We finalized for probation to mean that, for the applicable performance period, the third party intermediary must meet all applicable criteria for qualification and approval and also must submit a corrective action plan for remediation or correction of any deficiencies identified by CMS that resulted in the probation (81 FR 77548).

In addition, we finalized that if the third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, we would annotate the listing of qualified third party intermediaries on the CMS Web site, noting that the third party intermediary furnished data of poor quality and would place the entity on probation for the subsequent performance period.

Further, we finalized if the third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS for one additional performance period. After 2 years on probation, the third party intermediary would be disqualified for the subsequent performance period. Data errors affecting in excess of 5 percent of the MIPS eligible clinicians or groups submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation for the following performance period. In placing the third party intermediary on probation; we would notify the third party intermediary of the identified issues, at the time of discovery of such issues.

In addition, we finalized that if the third party intermediary does not submit an acceptable corrective action plan within 14 days of notification of the deficiencies and correct the deficiencies within 30 days or before the submission deadline—whichever is sooner, we may disqualify the third party intermediary from participating in MIPS for the current performance period or the following performance period, as applicable.

We note that MIPS eligible clinicians are ultimately responsible for the data that are submitted by their third party intermediaries and expect that MIPS eligible clinicians and groups should ultimately hold their third party intermediaries accountable for accurate reporting. We will consider cases of vendors leaving the marketplace during the performance period on a case by case basis, but would note that we will not consider cases prior to the performance period. We would however, need proof that the MIPS eligible clinician had an agreement in place with the vendor at the time of their withdrawal from the marketplace. We are not proposing any changes to the process of probation and disqualification of a third party intermediary in this proposed rule.

Commenters on the final rule requested that we provide opportunities for MIPS eligible clinicians and groups that discover an issue with their third party intermediary to change reporting methods and/or third party intermediaries without restriction on the eligible clinicians. We thank the commenters for their feedback and will take the comments into consideration in future rulemaking.

f. Auditing of Third Party Intermediaries Submitting MIPS Data

In the CY 2017 Quality Payment Program final rule (81 FR 77389), we finalized at § 414.1400(j) that any third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) must comply with the following procedures as a condition of their qualification and approval to participate in MIPS as a third party intermediary:

(1) The entity must make available to us the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information will include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and if available, email;

(2) The entity must retain all data submitted to us for MIPS for a minimum of 10 years; and

(3) For the purposes of auditing, we may request any records or data retained for the purposes of MIPS for up to 6 years and 3 months.

We are proposing to change § 414.1400(j)(2) to clarify that the entity must retain all data submitted to us for purposes of MIPS for a minimum of 10 years from the end of the MIPS performance period.

11. Public Reporting on Physician Compare

This section contains the approach for public reporting on Physician Compare for the CY 2018 Quality Payment Program final rule, including MIPS, APMs, and other information as required by the MACRA and building on the MACRA public reporting policies previously finalized (81 FR 77390 through 77399).

Physician Compare draws its operating authority from section 10331(a)(1) of the Affordable Care Act. As required by section 10331(a)(1) of the Affordable Care Act, by January 1, 2011, we developed a Physician Compare

Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other EPs who participate in the PQRS under section 1848 of the Act. More information about Physician Compare can be accessed on the Physician Compare Initiative Web site at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

The first phase of Physician Compare was launched on December 30, 2010 (*http://www.medicare.gov/physiciancompare*). Since the initial launch, Physician Compare has been continually improved and more information has been added. In December 2016, the site underwent a complete user-informed, evidenced-based redesign to further enhance usability and functionality on both desktop computers and mobile devices and to begin to prepare the site for the inclusion of more data as required by the MACRA.

Currently, Web site users can view information about approved Medicare clinicians, such as: Name; Medicare primary and secondary specialties; practice locations; group affiliations; hospital affiliations that link to the hospital's profile on Hospital Compare as available; Medicare assignment status; education; residency; and, American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), and American Board of Optometry (ABO) board certification information. For groups, users can view group names, specialties, practice locations, Medicare assignment status, and affiliated clinicians. In December 2016, we also added indicators on the results page to show those clinicians and groups that had performance scores available to view. We also included an indicator on profile pages to show those Medicare clinicians and groups that satisfactorily or successfully participated in a CMS quality program to indicate their commitment to quality.

Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare phased in public reporting of performance scores that provide comparable information on quality and patient experience measures for reporting periods beginning January 1, 2012. To the extent that scientifically sound measures are developed and are available, Physician Compare is required to include, to the extent practicable, the following types of measures for public reporting: Measures collected under PQRS and an assessment of efficiency, patient health outcomes, and patient experience, as specified. The first set of quality measures were publicly reported on Physician Compare in February 2014. Currently, Physician Compare publicly reports 91 group-level measures collected through either the Web Interface or registry for groups participating in 2015 under the PQRS, 19 quality measures for ACOs participating in the 2015 Shared Savings Program or Pioneer ACO program, and 90 individual clinician-level measures collected either through claims or registry for individual EPs participating in 2015 under the PQRS. In addition, 31 total individual clinician-level Qualified Clinical Data Registry (QCDR) non-PQRS measures are publicly available either through Physician Compare profile pages or 2015 QCDR Web sites. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122).

As finalized in the CY 2015 and CY 2016 PFS final rules (79 FR 67547 and 80 FR 70885, respectively), Physician Compare will continue to expand public reporting. This expansion includes publicly reporting both individual eligible professional (now referred to as eligible clinician) and group-level QCDR measures starting with 2016 data available for public reporting in late 2017, as well as the inclusion of a benchmark and 5-star rating in late 2017 based on 2016 data (80 FR 71125 and 71129), among other additions.

This expansion will continue under the MACRA. Sections 1848(q)(9)(A) and (D) of the Act facilitate the continuation of our phased approach to public reporting by requiring the Secretary to make available on the Physician Compare Web site, in an easily understandable format, individual MIPS eligible clinician and group performance information, including:

- The MIPS eligible clinician's final score;
- The MIPS eligible clinician's performance under each MIPS performance category (quality, cost, improvement activities, and advancing care information);
- Names of eligible clinicians in Advanced APMs and, to the extent feasible, the names of such Advanced APMs and the performance of such models; and,
- Aggregate information on the MIPS, posted periodically, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians for each performance category.

Initial plans to publicly report this performance information on Physician Compare were finalized in the CY 2017 Quality Payment Program final rule (81 FR 77390). The proposals related to each of these requirements for year 2 of the Quality Payment Program are addressed below in this section.

Section 1848(q)(9)(B) of the Act also requires that this information indicate, where appropriate, that publicized information may not be representative of the eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated. The information mandated for Physician Compare under section 1848(q)(9) of the Act will generally be publicly reported consistent with sections 10331(a)(2) and 10331(b) of the Affordable Care Act, and like all measure data included on Physician Compare, will be comparable. In addition, section 10331(b) of the Affordable Care Act requires that we include, to the extent practicable, processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. In addition to the public reporting standards identified in the Affordable Care Act—statistically valid and reliable data that are accurate and comparable—we have established a policy that, as determined through user testing, the data we disclose generally should resonate with and be accurately interpreted by Web site users to be included on Physician Compare profile pages. Together, we refer to these conditions as the Physician Compare public reporting standards (80 FR 71118 through 71120). Section 10331(d) of the Affordable Care Act also requires us to consider input from multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act. We continue to receive general input from stakeholders on Physician Compare through a variety of means, including rulemaking and different forms of stakeholder outreach (for example, Town Hall meetings, Open Door Forums, webinars, education and outreach, Technical Expert Panels, etc.).

In addition, section 1848(q)(9)(C) of the Act requires the Secretary to provide an opportunity for MIPS eligible clinicians to review the information that will be publicly reported prior to such information being made public. This is generally consistent with section 10331(a)(2) of the Affordable Care Act, under which we have established a 30-day preview period for all measurement performance data that allows physicians and other eligible clinicians to view

their data as it will appear on the Web site in advance of publication on Physician Compare (80 FR 77392). Section 1848(q)(9)(C) of the Act also requires that MIPS eligible clinicians be able to submit corrections for the information to be made public. We finalized a policy to extend the current Physician Compare 30-day preview period for MIPS eligible clinicians starting with data from the 2017 MIPS performance period, which is available for public reporting in late 2018. Therefore, we finalized a 30-day preview period in advance of the publication of data on Physician Compare (81 FR 77392).

We will coordinate data review and any relevant data resubmission or correction between Physician Compare and the four performance categories of MIPS. All data available for public reporting—measure rates, scores, and attestations, etc.—are available for review and correction during the targeted review process, which will begin at least 30 days in advance of the publication of new data. Data under review is not publicly reported until the review is complete. All corrected measure rates, scores, and attestations submitted as part of this process are available for public reporting. The technical details of the process are communicated directly to affected MIPS eligible clinicians and groups and detailed outside of rulemaking with specifics made public on the Physician Compare Initiative page on *www.cms.gov* and communicated through Physician Compare and other CMS listservs (81 FR 77391).

In addition, section 1848(q)(9)(D) of the Act requires that aggregate information on the MIPS be periodically posted on the Physician Compare Web site, including the range of final scores for all MIPS eligible clinicians and the range of performance for all MIPS eligible clinicians for each performance category.

Lastly, section 104(e) of the MACRA requires the Secretary to make publicly available, on an annual basis, in an easily understandable format, information for physicians and, as appropriate, other eligible clinicians related to items and services furnished to people with Medicare, and to include, at a minimum:

- Information on the number of services furnished under Part B, which may include information on the most frequent services furnished or groupings of services;
- Information on submitted charges and payments for Part B services; and,
- A unique identifier for the physician or other eligible clinician that is available to the public, such as an NPI.

The information is further required to be made searchable by at least specialty or type of physician or other eligible clinician; characteristics of the services furnished (such as, volume or groupings of services); and the location of the physician or other eligible clinician.

In accordance with section 104(e) of the MACRA, we finalized a policy in the CY 2016 PFS final rule (80 FR 71130) to add utilization data to the Physician Compare downloadable database. Utilization data is currently available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html*. This information is integrated on the Physician Compare Web site via the downloadable database each year using the most current data, starting with the 2016 data, targeted for initial release in late 2017 (80 FR 71130). Not all available data will be included. The specific HCPCS codes included are to be determined based on analysis of the available data, focusing on the most used codes. Additional details about the specific HCPCS codes that are included in the downloadable database will be provided to stakeholders in advance of data publication. All data available for public reporting—on the public-facing Web site pages or in the downloadable database—are available for review during the 30-day preview period.

We propose to revise the public reporting regulation at § 414.1395(a), to more completely and accurately reference the data available for public reporting on Physician Compare. We propose to modify § 414.1395(a) to remove from the heading and text references to ''MIPS'' and ''public Web site'' and instead reference ''Quality Payment Program'' and ''Physician Compare''. Specifically, proposed § 414.1395(a) reads as follows: ''Public reporting of eligible clinician and group Quality Payment Program information. For each program year, CMS posts on Physician Compare, in an easily understandable format, information regarding the performance of eligible clinicians or groups under the Quality Payment Program.'' We also propose to add paragraphs (b), (c), and (d) at § 414.1395, to capture previously established policies for Physician Compare relating to the public reporting standards, first year measures, and the 30-day preview period. Specifically, at proposed § 414.1395(b), we propose that, with the exception of data that must be mandatorily reported on Physician Compare, for each program year, we rely on the established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; be comparable across reporting mechanisms; and, meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with Web site users, as determined by CMS. At proposed § 414.1395(c), we propose to codify our policy regarding first year measures: ''For each program year, CMS does not publicly report any first year measure, meaning any measure in its first year of use in the quality and cost performance categories. After the first year, CMS reevaluates measures to determine when and if they are suitable for public reporting.'' At proposed § 414.1395(d), we propose to specify the 30-day preview period rule: ''For each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare.''

We believe section 10331 of the Affordable Care Act supports the overarching goals of the MACRA by providing the public with quality information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As such, we propose the inclusion of the following information on Physician Compare.

a. Final Score, Performance Categories, and Aggregate Information

Sections 1848(q)(9)(A) and (D) of the Act require that we publicly report on Physician Compare the final score for each MIPS eligible clinician, performance of each MIPS eligible clinician for each performance category, and periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category. We finalized such data for public reporting on Physician Compare for the transition year (81 FR 77393), and we are now proposing to add these data each year to Physician Compare for each MIPS eligible clinician or group, either on the profile pages or in the downloadable

database, as technically feasible. Statistical testing and user testing, as well as consultation of the Physician Compare Technical Expert Panel, will determine how and where these data are best reported on Physician Compare. As the MACRA requires that this information be available for public reporting on Physician Compare, we are proposing to include it each year moving forward, as technically feasible. We request comment on this proposal to publicly report on Physician Compare the final score for each MIPS eligible clinician or group, performance of each MIPS eligible clinician or group for each performance category, and periodically post aggregate information on the MIPS, including the range of final scores for and the range of performance of all the MIPS eligible clinicians or groups for each performance category, as technically feasible.

A detailed discussion of proposals related to each performance category of MIPS data follows.

b. Quality

As detailed in the CY 2017 Quality Payment Program final rule (81 FR 77395), and consistent with the existing policy that makes all current PQRS measures available for public reporting, we finalized a decision to make all measures under the MIPS quality performance category available for public reporting on Physician Compare in the transition year of the Quality Payment Program, as technically feasible. This included all available measures reported via all available submission methods, and applied to both MIPS eligible clinicians and groups.

Also consistent with current policy, although all measures will be available for public reporting, not all measures will be made available on the public-facing Web site profile pages. As explained in the CY 2017 Quality Payment Program final rule (81 FR 77394), providing too much information can overwhelm Web site users and lead to poor decision making. Therefore, consistent with section 1848(q)(9)(A)(i)(II) of the Act, all measures in the quality performance category that meet the statistical public reporting standards will be included in the downloadable database, as technically feasible. We also finalized a policy that a subset of these measures will be publicly reported on the Web site's profile pages, as technically feasible, based on Web site user testing. Statistical testing and user testing will determine how and where measures are reported on Physician Compare. In addition, we adopted our existing policy of not publicly reporting first year measures, meaning new measures that have been in use for less than 1 year, regardless of submission method used, for this MIPS quality performance category. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for public reporting (81 FR 77395).

Currently, there is a minimum sample size requirement of 20 patients for performance data to be included on Physician Compare. We previously sought comment on moving away from this requirement and moving to a reliability threshold for public reporting. In general, commenters supported a minimum reliability threshold. As a result, we finalized instituting a minimum reliability threshold for public reporting data on Physician Compare starting with 2017 data available for public report in late 2018 and each year moving forward (81 FR 77395).

The reliability of a measure refers to the extent to which the variation in the performance rate is due to variation in quality of care as opposed to random variation due to sampling. Statistically, reliability depends on performance variation for a measure across entities, the random variation in performance for a measure within an entity's panel of attributed patients, and the number of patients attributed to the entity. High reliability for a measure suggests that comparisons of relative performance across entities, such as eligible clinicians or groups, are likely to be stable and consistent, and that the performance of one entity on the quality measure can confidently be distinguished from another. We will conduct analyses to determine the reliability of the data collected and use this to calculate the minimum reliability threshold for the data. Once an appropriate minimum reliability threshold is determined, we will only publicly report those performance rates for any given measure that meet the minimum reliability threshold. We note that reliability standards for public reporting and reliability for scoring need not align; reliability for public reporting is unique because, for example, public reporting requires ensuring additional protections to maintain confidentiality. In addition, because publicly reported measures can be compared across clinicians and across groups, it is particularly important for the most stringent reliability standards to be in place to ensure differences in performance scores reflect true differences in quality of care to promote accurate comparisons by the public. For further information on reliability as it relates to scoring of cost measures see section II.C.7.a.(3) of this proposed rule.

In the CY 2017 Quality Payment Program final rule, we established that we will include the total number of patients reported on each measure in the downloadable database to facilitate transparency and more accurate understanding and use of the data (81 FR 77395). We will begin publishing the total number of patients reported on each measure in the downloadable database with 2017 data available for public reporting in late 2018 and for each year moving forward.

Understanding that we will continue our policies to not publicly report first year quality measures, that we will only report those measures that meet the reliability threshold and meet the public reporting standards, and include the total number of patients reported on for each measure in the downloadable database, we are again proposing to make all measures under the MIPS quality performance category available for public reporting on Physician Compare, as technically feasible. This would include all available measures reported via all available submission methods for both MIPS eligible clinicians and groups, for 2018 data available for public reporting in late 2019, and for each year moving forward, these data are required by the MACRA to be available for public reporting on Physician Compare, continuing to publicly report these data ensures continued transparency and provides people with Medicare and their caregivers valuable information they can use to make informed health care decisions. We request comment on this proposal.

In addition, we seek comment on expanding the patient experience data available for public reporting on Physician Compare. Currently, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey is available for groups to report under the MIPS. This patient experience survey data is highly valued by patients and their caregivers as they evaluate their health care options. However, in testing with patient and caregivers, they regularly ask for more information from patients like them in their own words. Patients regularly request we include narrative reviews of clinicians and groups on the Web site. The Agency for Healthcare Research and Quality (AHRQ) is fielding a beta version of the CAHPS Patient Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*). This includes five open-ended questions designed to be added to the Clinician &

Groups CAHPS survey, which CAHPS for MIPS is molded after. These five questions have been developed and tested to work to capture patient narratives in a scientifically grounded and rigorous way, setting it apart from other patient narratives collected by various health systems and patient rating sites. More scientifically rigorous patient narrative data would not only greatly benefit patients, but it would also greatly aid clinicians and groups as they work to assess how their patients experience care. We are seeking comment on potentially public reporting these five open-ended questions for the CAHPS for MIPS survey on Physician Compare as a consideration in future rulemaking. We direct readers to the Quality Performance Criteria in section II.C.6.b.(3)(a) of this proposed rule for additional information related to seeking comment on adding these questions to the CAHPS for MIPS survey.

c. Cost

Consistent with section 1848(q)(9)(A)(i)(II) of the Act, we finalized in the CY 2017 Quality Payment Program final rule a decision to make all measures under the MIPS cost performance category available for public reporting on Physician Compare (81 FR 77396). This included all available measures reported via all available submission methods, and applied to both MIPS eligible clinicians and groups. However, as noted in the final rule, we may not have data available for public reporting in the transition year of the Quality Payment Program for the cost performance category (2017 data available for public reporting in late 2018).

As discussed in the final rule (81 FR 77395), cost data are difficult for patients to understand and, as a result, publicly reporting these measures could lead to significant misinterpretation and misunderstanding. For this reason, we are again proposing to include on Physician Compare a sub-set of cost measures that meet the public reporting standards, either on profile pages or in the downloadable database, if technically feasible, for 2018 data available for public reporting in late 2019, and for each year moving forward. These data are required by the MACRA to be available for public reporting on Physician Compare, but we want to ensure we only share those cost measures that can help patients and caregivers make informed health care decisions on profile pages. For transparency purposes, the cost measures that meet all other public reporting standards would be included in the downloadable database. Statistical testing and Web site user testing would determine how and where measures are reported on Physician Compare to minimize passing the complexity of these measures on to patients and to ensure those measures included are accurately understood and correctly interpreted. Under this proposal, we note that the policies we previously mentioned regarding first year measures, the minimum reliability threshold, and all public reporting standards would apply. This proposal applies to all available measures reported via all available submission methods, and applies to both MIPS eligible clinicians and groups. We request comment on this proposal.

d. Improvement Activities

Consistent with section 1848(q)(9)(A)(i)(II) of the Act, we finalized a decision to make all activities under the MIPS improvement activities performance category available for public reporting on Physician Compare (81 FR 77396). This included all available improvement activities reported via all available submission methods, and applied to both MIPS eligible clinicians and groups.

Consistent with the policy finalized for the transition year, we are again proposing to include a subset of improvement activities data on Physician Compare that meet the public reporting standards, either on the profile pages or in the downloadable database, if technically feasible, for 2018 data available for public reporting in late 2019, and for each year moving forward. This again includes all available activities reported via all available submission methods, and applies to both MIPS eligible clinicians and groups. For those eligible clinicians or groups that successfully meet the improvement activities performance category requirements this information may be posted on Physician Compare as an indicator. This information is required by the MACRA to be available for public reporting on Physician Compare, but the improvement activities performance category is a new field of data for Physician Compare so concept and Web site user testing is still needed to ensure these data are understood by stakeholders. Therefore, we again propose that statistical testing and user testing would determine how and where improvement activities are reported on Physician Compare.

For the transition year, we proposed to exclude first year activities from public reporting. First year activities are any improvement activities in their first year of use. Starting with year 2 (2018 data available for public reporting in late 2019), we propose publicly reporting first year activities if all other reporting criteria are satisfied. This evolution in our Quality Payment Program public reporting plan provides an opportunity to make more valuable information public given that completion of or participation in activities the first year they are available is different from reporting first year quality or cost measures. Clinicians and groups can learn from the first year of quality and cost data, understand why their performance rate is what it is, and take time to improve. A waiting period for indicating completion or participation in an improvement activity is unlikely to produce the same benefit. We request comments on these proposals.

e. Advancing Care Information

Since the beginning of the EHR Incentive Programs in 2011, participant performance data has been publicly available in the form of public use files on the CMS Web site. In the 2015 EHR Incentive Programs final rule (80 FR 62901), we addressed comments requesting that we not only continue this practice but also include a wider range of information on participation and performance. In that rule, we stated our intent to publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with quality programs which utilize publicly available performance data such as Physician Compare. At this time there is only an indicator on Physician Compare profile pages to show that an eligible clinician successfully participated in the current Medicare EHR Incentive Program.

As MIPS will include advancing care information as one of the four MIPS performance categories, we decided, consistent with section 1848(q)(9)(i)(II) of the Act, to include more information on an eligible clinician's or group's performance on the objectives and measures of meaningful use on Physician Compare for the transition year (81 FR 77387). An important consideration was that to meet the public reporting standards, the data added to Physician Compare must resonate with Medicare patients and their caregivers. Testing to date has shown that people with Medicare value the use of certified EHR technology and see EHR use as something that if used well can improve the quality of their care. In addition, we believe the inclusion of indicators for clinicians and groups who achieve high

performance in key care coordination and patient engagement activities provide significant value for patients and their caregivers as they make health care decisions.

Consistent with our transition year final policy, and understanding the value of this information to Web site users, we are again proposing to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the advancing care information performance category, as technically feasible. Also, as technically feasible, we propose to include additional indicators, including but not limited to, objectives, activities, or measures specified in section II.C.6.f. of this proposed rule, such as, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. These proposals would apply to 2018 data available for public reporting in late 2019, and for each year moving forward, as this information is required by the MACRA to be available for public reporting on Physician Compare. We also propose that any advancing care information objectives, activities, or measures would need to meet the public reporting standards applicable to data posted on Physician Compare, either on the profile pages or in the downloadable database. This would include all available objectives, activities, or measures reported via all available submission methods, and would apply to both MIPS eligible clinicians and groups. Statistical testing and Web site user testing would determine how and where objectives and measures are reported on Physician Compare. As with improvement activities, we are also proposing to allow first year advancing care information objectives, activities, and measures to be available for public reporting starting in year 2 (2018 data available for public reporting in late 2019). Again, especially if we are including an indicator over a performance rate, the benefits of waiting 1 year are not the same and thus, we believe it is more important to make more information available for public reporting as the Quality Payment Program matures. We request comment on these proposals.

f. Achievable Benchmark of Care (ABC™)

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows Web site users to more easily evaluate the information published by providing a point of comparison between groups and between clinicians. In an effort to find the best possible methodology for Physician Compare, we embarked on a year-long information gathering and stakeholder outreach effort in advance of the CY 2016 PFS rule process. We reached out to stakeholders, including specialty societies, consumer advocacy groups, physicians and other clinicians, measure experts, and quality measure specialists, as well as other CMS Quality Programs. Based on this outreach and the recommendation of our Technical Expert Panel, we proposed and ultimately finalized (80 FR 71129) a decision to publicly report on Physician Compare an item, or measure-level, benchmark using the Achievable Benchmark of Care (ABC™) [21] methodology annually based on the PQRS performance rates most recently available by reporting mechanism. As a result, in late 2017, we expect to publicly report a benchmark based on the 2016 PQRS performance rates for each measure by each available reporting mechanism. The specific measures the benchmark will be calculated for will be determined once the data are available and analyzed. As with all data, the benchmark will only be applied to those measures deemed to meet the established public reporting standards.

We believe ABC™ is a well-tested, data-driven methodology that allows us to account for all of the data collected for a quality measure, evaluate who the top performers are, and then use that to set a point of comparison for all of those groups or clinicians who report the measure.

ABC™ starts with the pared-mean, which is the mean of the best performers on a given measure for at least 10 percent of the patient population—not the population of reporters. To find the pared-mean, we will rank order physicians or groups (as appropriate per the measure being evaluated) in order from highest to lowest performance score. We will then subset the list by taking the best performers moving down from best to worst until we have selected enough reporters to represent 10 percent of all patients in the denominator across all reporters for that measure.

We finalized that the benchmark would be derived by calculating the total number of patients in the highest scoring subset receiving the intervention or the desired level of care, or achieving the desired outcome, and dividing this number by the total number of patients that were measured by the top performing doctors. This would produce a benchmark that represents the best care provided to the top 10 percent of patients by measure, by reporting mechanism.

An Example: A clinician reports on how many patients with diabetes she has given foot exams. There are four steps to establishing the benchmark for this measure.

(1) We look at the total number of patients with diabetes for all clinicians who reported this diabetes measure.

(2) We rank clinicians that reported this diabetes measure from highest performance score to lowest performance score to identify the set of top clinicians who treated at least 10 percent of the total number of patients with diabetes.

(3) We count how many of the patients with diabetes who were treated by the top clinicians also got a foot exam.

(4) This number is divided by the total number of patients with diabetes who were treated by the top clinicians, producing the ABC™ benchmark.

To account for low denominators, ABC™ suggests the calculation of an adjusted performance fraction (AFP) using a Bayesian Estimator or use of another statistical methodology. After analysis, we have determined that the use of a beta binomial model adjustment is most appropriate for the type of data we are working with. The beta binomial method moves extreme values toward the average for a given measure, while the Bayesian Estimator moves extreme values toward 50 percent. Using the beta binomial method is a more methodologically sophisticated approach to address the issue of extreme values based on small sample sizes. This ensures that all clinicians are accounted for and appropriately figured in to the benchmark.

The benchmarks for Physician Compare developed using the ABC™ methodology will be based on the current year's data, so the benchmark will be appropriate regardless of the unique circumstances of data collection or the measures available in a given reporting year. We also finalized (80 FR 71129) a decision to use the ABC™ methodology to generate a benchmark which will be used to systematically assign stars for the Physician Compare 5-star rating. The details of how the benchmark will be specifically used to determine the 5-star categories for all applicable measures is being determined in close collaboration with stakeholders, CMS programs, measure experts, and the Physician Compare

[21] Kiefe CI, Weissman NW., Allison JJ, Farmer R, Weaver M, Williams OD. Identifying achievable benchmarks of care: concepts and methodology. International Journal of Quality Health Care. 1998 Oct; 10(5):443–7.

Technical Expert Panel. We expect to publicly report the benchmark and 5-star rating for the first time on Physician Compare in late 2017 using the 2016 PQRS performance scores for both clinicians and groups.

As a result of stakeholder feedback asking that we consider one consistent approach for benchmarking and parsing the data based on the benchmark across the Quality Payment Program, we did consider an alternative approach. We reviewed the benchmark and decile breaks being used to assign points and determine payment under MIPS (see II.C.7.a.(2)(b) of this proposed rule). This approach was not considered ideal for public reporting for several reasons. A primary concern was that the decile approach when used for public reporting would force a star rating distribution inconsistent with the raw distribution of scores on a given measure. If applied to star ratings, there would need to be an equal distribution of clinicians in each of the star rating categories.

Using the ABC™ methodology for the benchmark sets the 5-star rating at the performance rate that is the best achievable rate in the current clinical climate based on the current set of measures and the current universe of reporters. The star ratings are then derived from there consistent with the raw score distribution. In this way, if the majority of clinicians performed well on a measure, the majority would receive a high star rating. If we used the decile approach some clinicians would be reported as having a ''low'' star rating despite their relative performance on the measure.

It is not always ideal to use the same methodology across the program as scoring for payment purposes may be designed in a somewhat different way that may incorporate factors that are not necessarily as applicable for public reporting, while the key consideration for public reporting is that the methodology used best helps patients and caregivers easily interpret the data accurately. Testing with Web site users has shown that the star rating based on the ABC™ benchmark helps patients and caregivers interpret the data accurately.

ABC™ has been historically well received by the clinicians and entities it is measuring because the benchmark represents quality while being both realistic and achievable; it encourages continuous quality improvement; and, it is shown to lead to improved quality of care.[22] [23] [24] Appreciating this and the support this methodology received in previous rulemaking and throughout our outreach process to date, we are again proposing to use the ABC™ methodology to determine a benchmark for the quality, cost, improvement activities, and advancing care information data, as feasible and appropriate, by measure and by reporting mechanism for each year of the Quality Payment Program, starting with the transition year data (2017 data available for public reporting in late 2018). We are also proposing to use this benchmark to determine a 5-star rating for each MIPS measure, as feasible and appropriate. As previously finalized, only those measures that meet the public reporting standards would be considered and the benchmark would be based on the most recently available data. The details of how the benchmark will translate to the 5-star rating will be determined in consultation with stakeholders.

We believe that displaying the appropriate and relevant MIPS data in this user-friendly format provides more opportunities to present these data to people with Medicare in a way that is most likely to be accurately understood and interpreted. We request comment on these proposals.

g. Voluntary Reporting

In CY 2017 Quality Payment Program proposed rule (81 FR 28291), we solicited comment on the advisability and technical feasibility of including on Physician Compare data voluntarily reported by eligible clinicians and groups that are not subject to MIPS payment adjustments, such as exempt clinician types and those clinicians practicing through Rural Health Centers (RHCs), Federally Qualified Health Centers (FQHCs), etc., to be addressed through separate notice-and-comment rulemaking.

Overall, comments received were favorable. Stakeholders generally support clinicians and groups being permitted to have data available for public reporting when submitting these data voluntarily under MIPS. As a result, we are now proposing that starting with year 2 of the Quality Payment Program (2018 data available for public reporting in 2019) and for each year moving forward, to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of submission method, by clinician and groups not subject to the MIPS payment adjustments, as technically feasible.

If a clinician or group chooses to submit quality, cost, improvement activity, or advancing care information, these data would become available for public reporting. However, because these data would be submitted voluntarily, we propose that during the 30-day preview period these clinicians and groups would have the option to opt out of having their data publicly reported on Physician Compare. If clinicians and groups do not actively opt out at this time, their data would be available for inclusion on Physician Compare if the data meet all previously stated public reporting standards and the minimum reliability threshold. As clinicians and groups not required to report under MIPS, particularly in the first years of the Quality Payment Program, are taking additional steps to show their commitment to quality care, we want to ensure they have the opportunity to report their data and have it included on Physician Compare. We request comment on this proposal.

h. APM Data

Section 1848(q)(9)(A)(ii) of the Act requires us to publicly report names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of Advanced APMs. We see this as an opportunity to continue to build on the ACO reporting we are now doing on Physician Compare. At this time, if a clinician or group submitted quality data as part of an ACO, there is an indicator on the clinician's or group's profile page indicating this. In this way, it is known which clinicians and groups took part in an ACO. Also, currently, all ACOs have a dedicated page on the Physician Compare Web site to showcase their data. For the transition year of the Quality Payment Program, we decided to use this model as a guide as we add APM data to Physician Compare. Specifically, we finalized a policy to indicate on eligible clinician and group profile pages of Physician Compare when the eligible clinician or group is participating in an APM (81 FR 77398). We also finalized a decision to link eligible clinicians and groups to their APM's data, as technically feasible, through Physician Compare. The finalized policy provides the opportunity to publicly report data for

[22] Kiefe CI, Weissman NW., Allison JJ, Farmer R, Weaver M, Williams OD. Identifying achievable benchmarks of care: concepts and methodology. International Journal of Quality Health Care. 1998 Oct; 10(5):443–7.

[23] Kiefe CI, Allison JJ, Williams O, Person SD, Weaver MT, Weissman NW. Improving Quality Improvement Using Achievable Benchmarks For Physician Feedback: A Randomized Controlled Trial. JAMA. 2001;285(22):2871–2879.

[24] Wessell AM, Liszka HA, Nietert PJ, Jenkins RG, Nemeth LS, Ornstein S. Achievable benchmarks of care for primary care quality indicators in a practice-based research network. American Journal of Medical Quality 2008 Jan–Feb;23(1):39–46.

both Advanced APMs and APMs that are not considered Advanced APMs for the transition year, as technically feasible.

At the outset, APMs will be very new concepts for Medicare patients and their caregivers. In these early years, indicating who participated in APMs and testing language to accurately explain that to Web site users provides useful and valuable information as we continue to evolve Physician Compare. As we come to understand how to best explain this concept to patients and their caregivers, we can continue to assess how to most fully integrate these data on the Web site. Understanding this and understanding the value of adding APM data to Physician Compare, we are again proposing to publicly report names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not considered Advanced APMs related to the Quality Payment Program starting with year 2 (2018 data available for public reporting in late 2019), and for each year moving forward, as technically feasible. In addition, we again propose to continue to find ways to more clearly link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible. We request comment on these proposals.

i. Stratification by Social Risk Factors

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support play a major role in health. One of our core objectives is to improve the outcomes of people with Medicare, and we want to ensure that complex patients, as well as those with social risk factors receive excellent care. In addition, we seek to ensure that all clinicians are treated as fairly as possible within all CMS programs. In the CY 2017 Quality Payment Program final rule (81 FR 77395), we noted that we would review the first of several reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE).[25] In addition, we have been reviewing the report of the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS programs. ASPE's first report, as required by the Improving Medicare Post-Acute Care Treatment (IMPACT) Act, was released on December 21, 2016, and analyzed the effects of social risk factors of people with Medicare on clinician performance under nine Medicare value-based purchasing programs. A second report due October 2019 will expand on these initial analyses, supplemented with non-Medicare datasets to measure social risk factors. The National Academies of Sciences, Engineers, and Medicine released its fifth and final report on January 10, 2017, and provided various potential methods for accounting for social risk factors, including stratified public reporting, as well as recommended next steps.[26]

As we continue to consider the analyses and recommendations from these and any future reports, we look forward to working with stakeholders in this process. Therefore, we seek comment only on accounting for social risk factors through public reporting on Physician Compare. Specifically, we seek comment on stratified public reporting by risk factors and ask for feedback on which social risk factors or indicators should be used and from what sources. Examples of social risk factor indicators include but are not limited to dual eligibility/low-income subsidy, race and ethnicity, social support, and geographic area of residence. We also seek comment on the process for accessing or receiving the necessary data to facilitate stratified reporting. Finally, we seek comment on whether strategies such as confidential reporting of stratified rates using social risk factor indicators should be considered in the initial years of the Quality Payment Program in lieu of publicly reporting stratified performance rates for quality and cost measures under the MIPS on Physician Compare. We seek comment only on these items for possible consideration in future rulemaking.

j. Board Certification

Finally, we propose adding additional Board Certification information to the Physician Compare Web site. Board Certification is the process of reviewing and certifying the qualifications of a physician or clinician by a board of specialists in the relevant field. We currently include ABMS, AOA, and ABO data as part of clinician profiles on Physician Compare. We appreciate that there are additional, well respected boards that are not included in the ABMS, AOA, and ABO data currently available on Physician Compare that represent clinicians and specialties represented on the Web site. Such board certification information is of interest to users as it provides additional information to use to evaluate and distinguish between clinicians on the Web site, which can help in making an informed health care decision. The more data of immediate interest that is included on Physician Compare, the more users will come to the Web site and find quality data that can help them make informed decisions. Please note we are not endorsing any particular boards.

Another board, the American Board of Wound Medicine and Surgery (ABWMS), has shown interest in being added to Physician Compare and have demonstrated that they have the data to facilitate inclusion of this information on the Web site. We believe this board fills a gap for a specialty that is not currently covered by the ABMS, so we propose to add ABWMS Board Certification information to Physician Compare.

Additionally, for all years moving forward, for any board that would like to be considered to be added to the Physician Compare Web site, we propose to establish a process for reviewing interest from these boards as it is brought to our attention on a case-by-case basis, and selecting boards as possible sources of additional board certification information for Physician Compare. We further propose that, for purposes of CMS's selection, the board would need to demonstrate that it: Fills a gap in currently available board certification information listed on Physician Compare, can make the necessary data available, and if appropriate, can make arrangements and enter into agreements to share the needed information for inclusion on Physician Compare. We propose that boards contact the Physician Compare support team at *PhysicianCompare@Westat.com* to indicate interest and initiate the review and discussion process. Once decisions are made, they will be communicated via the *CMS.gov* Physician Compare initiative Web page and via the Physician Compare listserv. We request comments on these proposals.

D. Overview of the APM Incentive

1. Overview

Section 1833(z) of the Act requires that an incentive payment be made to QPs for participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized policies relating to the following topics:

[25] ASPE, ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' 21 Dec 2016. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[26] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

• Beginning in 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements in the performance year and payment adjustment for the payment year.

• For years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's payments for Part B covered professional services. Beginning in 2026, QPs receive a higher update under the PFS for the year than non-QPs.

• For 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.

• For 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In this proposed rule, we discuss proposals for clarifications and modifications to some of the policies that we previously finalized, and provide additional details and proposals regarding the All-Payer Combination Option.

2. Terms and Definitions

As we continue to develop the Quality Payment Program, we have identified the need to propose additions, deletions, and changes to some of the previously finalized definitions. A list of these definitions is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540).

As we discuss in section II.D.6.d.(2)(a) of this proposed rule, we propose to change the timeframe of the QP Performance Period under the All-Payer Combination Option so that it would begin on January 1 and end on June 30 of the calendar year that is 2 years prior to the payment year. We propose to add the definition of All-Payer QP Performance Period using this timeframe. We also propose to add the definition of Medicare QP Performance Period, which would begin on January 1 and end on August 31 of the calendar year that is 2 years prior to the payment year. We would replace the definition we established in the CY 2017 Quality Payment Program final rule for QP Performance Period with the definitions of All-Payer QP Performance Period and Medicare QP Performance Period. To update the regulation to incorporate this proposal, we also propose to remove ''QP Performance Period'' each time it occurs in our regulations and replace it with either ''All-Payer QP Performance Period'' or ''Medicare QP Performance Period'' as relevant. As we discuss in section II.D.6.d.(3)(a) of this proposed rule, we propose to make QP determinations under the All-Payer Combination Option at the eligible clincian level only. In connection with our proposals to calculate Threshold Scores for QP determinations under the All-Payer Combination Option, we do not anticipate having or receiving information about attributed beneficiaries as we do under the Medicare Option. This is because, under the All-Payer Combination Option, APM Entities or eligible clinicians would only submit aggregate payment and patient data. We would not have anything similar to a Participation List or an Affiliated Practitioner List for Other Payer Advanced APMs. Therefore, we are proposing to change the definition of attributed beneficiary so that it only applies to Advanced APMs, not to Other Payer Advanced APMs. We seek comment on these proposals.

We seek comment on these terms, including how we have defined the terms, the relationship between terms, any additional terms that we should formally define to clarify the explanation and implementation of this program, and potential conflicts with other terms we use in similar contexts. We also seek comment on the naming of the terms and whether there are ways to name or describe their relationships to one another that make the definitions more distinct and easier to understand. For instance, we would consider options for a framework of definitions that might more intuitively distinguish between APMs and Other Payer Advanced APMs and between APMs and Advanced APMs.

3. Regulation Text Changes

a. Clarifications and Corrections

We propose to revise the definition of APM Entity in the regulation at § 414.1305 to clarify that a ''payment arrangement with a non-Medicare payer'' is an other payer arrangement as defined in § 414.1305. We propose to make technical changes to the definition of Medicaid APM in § 414.1305 to clarify that these arrangements must meet the Other Payer Advanced APM criteria set forth in § 414.1420, and not just the criteria under § 414.1420(a) as provided under the current definition.

To consolidate our regulations and avoid unnecessarily defining a term, we propose to remove the defined term for Advanced APM Entity in § 414.1305 and to replace ''Advanced APM Entity'' where it appears throughout the regulations with ''APM Entity.'' We also propose to make this substitution in the definitions of Affiliated Practitioner and Attributed Beneficiary in § 414.1305. Similarly, we propose to replace ''Advanced APM Entity group'' with ''APM Entity group'' where it appears throughout our regulations. We note that these proposed changes are technical, and would not have a substantive effect on our policies.

We propose technical changes to correct the references in the first sentence of the regulation at § 414.1415 to refer to the financial risk standard under paragraph (c)(1) or (2) and the nominal amount standard under paragraph (c)(3) or (4). Due to typographical errors, the current regulation refers to paragraphs (d)(1) through (4), and there is no paragraph (d) in this section. We also propose to correct typographical errors in § 414.1420(a)(3)(i), (ii), (d) and (d)(1). In § 414.1420(d), we propose to correct the reference to the ''nominal risk standard'' to instead refer to the ''nominal amount standard.'' We propose technical, non-substantive clarifications in §§ 414.1425(a)(1) through (3), 414.1425(b)(2), and 414.1435(d). We also propose to correct a typographical error in § 414.1460(b) to refer to participation ''during a Medicare QP Performance Period'' instead of ''during the QP Performance Periods.''

b. Changes to § 414.1460

We propose to reorganize and revise the monitoring and program integrity provisions at § 414.1460. We propose changes to paragraphs (a), (b), and (d) in this section of the proposed rule as these policies apply to both the Medicare Option and the All-Payer Combination Option. We discuss proposed changes to paragraph (c) of § 414.1460 in sections II.D.6.c.(7) and II.D.6.d.(4) of this proposed rule, and changes to paragraph (e) of § 414.1460 in sections II.D.6.c.(7)(b) and II.D.6.d.(4)(c), as the policies in these paragraphs only apply to the All-Payer Combination Option.

We finalized in the CY 2017 Quality Payment Program final rule at § 414.1460(d) that for any QPs who are terminated from an Advanced APM or found to be in violation of any federal, state, or tribal statute, regulation, or binding guidance during the QP Performance Period or Incentive Payment Base Period or terminated after these periods as a result of a violation occurring during either period we may rescind such eligible clinician's QP determinations and, if necessary, recoup

part or all of any such eligible clinician's APM Incentive Payment or deduct such amount from future payments to such individuals. We also finalized that we may reopen and recoup any payments that were made in error (81 FR 77555). We recognize that rescinding QP determinations and reopening and recouping APM Incentive Payments are separate policies and for this reason, we propose to reorganize § 414.1460 so that paragraph (b) sets forth our policy on rescinding QP determinations and paragraph (d) sets forth our policy on reopening and recouping APM Incentive Payments. We propose to revise § 414.1460(b) to provide when we may rescind a QP determination. In addition, we propose to remove the last sentence of § 414.1460(d), which provides that an APM Incentive Payment will be recouped if an audit reveals a lack of support for attested statements provided by eligible clinicians and APM Entitles. We believe that this provision is duplicative of the immediately preceding sentence, which permits us to reopen and recoup any erroneous payments in accordance with existing procedures set forth at §§ 405.980 through 405.986 and 405.370 through 405.379. We propose to codify our recoupment policy at § 414.1460(d)(2), which provides that we may reopen, revise, and recoup an APM Incentive Payment that was made in error in accordance with procedures similar to those set forth at §§ 405.980 through 405.986 and 405.370 through 405.379 or as established under the relevant APM.

In the CY 2017 Quality Payment Program final rule, we indicated at § 414.1460(b) that CMS may reduce or deny an APM Incentive Payment to eligible clinicians who are terminated by APMs or whose APM Entities are terminated by APMs for non-compliance with all Medicare conditions of participation or the terms of the relevant Advanced APMs in which they participate during the QP Performance Period. We also finalized at § 414.1460(a) that for QPs who CMS determines are not in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APMs in which they participate during the QP Performance Period, there may be a reduction or denial of the APM Incentive Payment. We propose to consolidate our policy on reducing and denying APM Incentive Payments and redesignate it to § 414.1460(d)(1). Thus, we propose to remove provisions regarding reducing and denying APM Incentive Payments from paragraphs (a) and (b) of § 414.1460, and revise paragraph (d) to discuss when CMS may reduce or deny an APM Incentive Payment to an eligible clinician. We solicit comment on these proposals.

4. Advanced APMs

a. Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (See 81 FR 77409–44414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (See 81 FR 77414–77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or the APM is a Medical Home Model expanded under section 1115A(c) of the Act (See 81 FR 77418–77431).

APMs may offer multiple options or tracks with variations in CEHRT use requirements, quality-based payments, and the level of financial risk; or multiple tracks designed for different types of participant organizations, and we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77406) that we will consider different tracks or options within an APM separately for purposes of making Advanced APM determinations.

b. Bearing Financial Risk for Monetary Losses

In the CY 2017 Quality Payment Program final rule (81 FR 77418), we divided the discussion of this criterion into two main elements: (1) What it means for an APM Entity to bear financial risk for monetary losses under an APM); and (2) what levels of risk we would consider to be in excess of a nominal amount. For each of these elements, we established a generally applicable standard and a Medical Home Model standard.

As we discussed in the CY 2017 Quality Payment Program final rule, we believe that it is important to maintain the distinction between Medical Home Models and other APMs because we believe that Medical Home Models are categorically different than other types of APMs, as supported by specific provisions in the statute enabling unique treatment of Medical Home Models. Also, Medical Home Model participants tend to be smaller in size and have lower Medicare revenues relative to total Medicare spending than other APM Entities, which affects their ability to bear substantial risk, especially in relation to total cost of care. We believe that the meaning of nominal financial risk varies according to context, and that smaller practices participating in Medical Home Models, as a category, experience risk differently than much larger, multispecialty focused organizations do. Historically, Medical Home Model participants have not been required to bear financial risk, which means the assumption of any new financial risk presents a new challenge for these entities (81 FR 77420–77421). For these reasons, we finalized special standards for Medical Home Models that are exceptions to the generally applicable financial risk and nominal amount standards.

(1) Medical Home Model Eligible Clinician Limit

In the CY 2017 Quality Payment Program final rule, we finalized that beginning in the 2018 Medicare QP Performance Period, the Medical Home Model financial risk standard would only apply to APM Entities that participate in Medical Home Models and that have fewer than 50 eligible clinicians in the organization through which the APM Entity is owned and operated (81 FR 77430). Under this policy, in a Medical Home Model that otherwise meets the criteria to be an Advanced APM, the Medical Home Model financial risk standard would be applicable only for those APM Entities owned and operated by organizations with fewer than 50 eligible clinicians. We note this policy does not apply to Medical Home Models expanded under section 1115A of the Act.

We are proposing to exempt from this requirement any APM Entities enrolled in Round 1 of the Comprehensive Primary Care Plus Model (CPC+).

We finalized the Medical Home Model eligible clinician limit after practices applied and signed agreements with CMS to participate in CPC+ Round 1. As such, practices applying to participate in CPC+ Round 1 were not necessarily aware of the eligible clinician limit policy and will have already participated in CPC+ for one year without this requirement applying to them by the beginning of CY 2018. Thus, to permit continued and uninterrupted testing of CPC+ in existing regions, we believe it is necessary to exempt practices participating in CPC+ Round 1 from this requirement. Additionally, since in future all APM Entities would know about this requirement prior to their

enrollment and in order to ensure that large APM entities that are able to bear more risk enroll in such higher risk models, we are also proposing that CPC+ participants who enroll in the future (for example, in CPC+ Round 2) will not be exempt from this requirement. While this creates a small difference between the incentives for large APM Entities in different cohorts to participate in CPC+, we believe an APM Entity should seek to enroll in an APM, including an Advanced APM, primarily based on the framework of that APM itself, rather than the possibility of other associated payments such as the Advanced APM incentive payment. Additionally, we note that any eligible clinicians in APM Entities participating in CPC+ that do not achieve QP status for the year would be scored under MIPS using the APM scoring standard, meaning minimal additional burden would be required for such MIPS eligible clinicians.

We seek comment on these proposals.

(2) Nominal Amount of Risk

We finalized in the CY 2017 Quality Payment Program final rule (81 FR 77427) that an APM would meet the generally applicable nominal amount standard if, under the terms of the APM, the total annual amount that an APM Entity potentially owes us or foregoes is equal to at least:

- For QP Performance Periods in 2017 and 2018, 8 percent of the average estimated total Medicare Parts A and B revenue of participating APM Entities (the revenue-based standard); or
- For all QP Performance Periods, 3 percent of the expected expenditures for which an APM Entity is responsible under the APM (the benchmark-based standard).

We also finalized in the CY 2017 Quality Payment Program final rule (81 FR 77428) that to be an Advanced APM, a Medical Home Model must require that the total annual amount that an Advanced APM potentially owes us or foregoes under the Medical Home Model be at least the following amounts in a given performance year:

- In 2017, 2.5 percent of the APM Entity's total Medicare Parts A and B revenue.
- In 2018, 3 percent of the APM Entity's total Medicare Parts A and B revenue.
- In 2019, 4 percent of APM Entity's total Medicare Parts A and B revenue.
- In 2020 and later, 5 percent of the APM Entity's total Medicare Parts A and B revenue.

Both the generally applicable and Medical Home Model revenue-based nominal amount standards state the standard in terms of average estimated total Medicare Parts A and B revenue of participating APM Entities. We recognize that this language may be ambiguous as to whether it is intended to include payments to all providers and suppliers in an APM Entity or only payments directly to the APM Entity itself. To eliminate this potential ambiguity, we propose to amend §§ 414.1415(c)(3)(i)(A) and (c)(4)(i)(A) through (D) to more clearly define the generally applicable revenue-based nominal amount standard and the Medical Home Model revenue-based nominal amount standard as a percentage of the average estimated total Medicare Parts A and B revenue of providers and suppliers in participating APM Entities. Under this proposed policy, when assessing whether an APM meets the generally applicable revenue-based nominal amount standard, where total risk under the model is not expressly defined in terms of revenue, we would calculate the estimated total Medicare Parts A and B revenue of providers and suppliers at risk for each APM Entity. We would then calculate an average of all the estimated total Medicare Parts A and B revenue of providers and suppliers at risk for each APM Entity, and if that average estimated total Medicare Parts A and B revenue at risk for all APM Entities was equal to or greater than 8 percent, the APM would satisfy the generally applicable revenue-based nominal amount standard.

We request comment on this proposal.

(a) Generally Applicable Revenue-Based Nominal Amount Standard

In the CY 2017 Quality Payment Program final rule we finalized the amount of the generally applicable revenue-based nominal amount standard for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on: (1) Setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

Many commenters requested that we not raise the revenue-based nominal amount standard for 2019 and beyond. Some commenters stated that maintaining the 8 percent revenue-based nominal amount standard for 2019 would allow for stability and predictability for eligible clinicians participating in certain APMs. Other commenters noted that increasing the revenue-based nominal amount standard may reduce or discourage eligible clinicians from participating in Advanced APMs and that the added complexity of requiring that a 10 percent revenue-based standard also be equivalent to at least 1.5 percent of expected expenditures would be confusing for participants and other stakeholders. A few commenters suggested that we only consider increasing the revenue-based nominal amount standard after we review how the finalized standard affects participation in Advanced APMs.

We agree that maintaining the revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of providers and suppliers in participating APM Entities would provide stability and clarity for eligible clinicians and APM Entities. We also continue to believe that 8 percent of the average estimated total Medicare Parts A and B revenue of providers and suppliers in participating APM Entities represents a reasonable standard to determine what constitutes a more than nominal amount of financial risk. We believe that the continued testing and evaluation of APMs with two-sided risk will yield critical information about the best way to structure financial incentives and financial risk, and this information may have bearing on what constitutes a more than nominal amount of risk. Therefore, we will continue to evaluate the revenue-based nominal amount standard in light of participation in Advanced APMs before considering any increase in later years.

After considering public comments submitted on the potential options for increasing the revenue-based nominal amount standard for Medicare QP Performance Periods 2019 and later, we propose to maintain the current revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the 2019 and 2020 Medicare QP Performance Periods, and to address the standard for Medicare QP Performance Periods after 2020 through subsequent rulemaking. We seek comment on whether we should consider either a lower or higher revenue-based nominal amount standard for the 2019 and 2020 Medicare QP Performance Periods, and on the amount and structure of the revenue-based nominal amount standard for Medicare QP Performance Periods 2021 and later.

We also seek comment on whether we should consider a different, potentially lower, revenue-based nominal amount standard only for small practices and those in rural areas that are not participating in a Medical Home Model for the 2019 and 2020 Medicare QP Performance Periods. For the purposes of the Quality Payment Program, we use the definition of small practices and rural areas in § 414.1305. Specifically, we seek comment on whether such a standard should apply only to small and, or rural practices that are participants in an APM, or also small and, or rural practices that join larger APM Entities in order to participate in APMs. We also seek comment on how we should decide where a practice is located in order to determine whether it is operating in a rural area as rural area is defined in § 414.1305 of our regulations. We believe that a different, potentially lower, revenue-based nominal amount standard for the 2019 and 2020 Medicare QP Performance Periods specifically for small practices and those in rural areas that are not participating in a Medical Home Model may allow for their increased participation in Advanced APMs, which may help increase the quality and coordination of care beneficiaries receive as a result. We believe such a standard should not apply to small and, or rural practices participating in a Medical Home Model because participants in Medical Home Models with fewer than 50 eligible clinicians in their parent organization benefit from the lower Medical Home Model nominal amount standard. We also note that such a standard may have certain disadvantages, including reducing the likelihood that potential Advanced APMs will ultimately result in reductions in the growth of Medicare expenditures and increasing the complexity of the generally applicable nominal amount standard.

(b) Medical Home Model Nominal Amount Standard

In the CY 2017 Quality Payment Program final rule, we finalized that if the financial risk arrangement under the Medical Home Model is not based on revenue (for example, it is based on total cost of care or a per beneficiary per month dollar amount), we will make a determination for the APM based on the risk under the Medical Home Model compared to the average estimated total Parts A and B revenue of its participating APM Entities using the most recently available data (81 FR 77428).

We received comments suggesting that few APM Entities in Medical Home Models have had experience with financial risk, and that many would be financially challenged to provide sufficient care or even remain a viable business if they were faced with the kinds of substantial disruptions in revenue that can accompany financial risk arrangements. Some commenters indicated that taking on the level of risk required under our finalized policy would still represent an increase in total risk that is too great in magnitude and premature for the many APM Entities in Medical Home Models that have little experience with financial risk.

We recognize these concerns, however, we still believe that a final Medical Home Model nominal amount standard of 5 percent is the appropriate target for the standard, and that ultimately setting the standard at 5 percent of Parts A and B revenue of providers and suppliers in participating APM Entities would strike the appropriate balance to reflect the meaning of ''nominal'' in the Medical Home Model context. We continue to believe that the meaning of the term ''nominal'' depends on the situation in which it is applied, so it is appropriate to consider the characteristics of Medical Home Models and their participating APM Entities in setting the nominal amount standard for Medical Home Models.

We have reconsidered the incremental annual increases in the nominal amount standard that we finalized to occur over several years from 2.5 percent to 5 percent. We recognize that establishing an even more gradual increase in risk for Medical Home Models with a lower risk floor for the 2018 Medicare QP Performance Period may be better suited to the circumstances of many APM Entities in Medical Home Models that have little experience with risk. We also reiterate, as we note for the generally applicable nominal amount standard, that the terms and conditions in the particular APM govern the actual risk that participants experience; the nominal amount standard merely sets a floor on the level of risk required for the APM to be considered an Advanced APM. To that end, we believe a small reduction of risk in the Medical Home Model nominal amount standard beginning in the 2018 Medicare QP Performance Period, along with a more gradual progression toward the 5 percent nominal amount standard, would allow for greater flexibility at the APM level in setting financial risk thresholds that would encourage more participation in Medical Home Models and be more sustainable for the type of APM Entities that would potentially participate in Medical Home Models.

Therefore, we are proposing that to be an Advanced APM, a Medical Home Model must require that the total annual amount that an APM Entity potentially owes us or foregoes under the Medical Home Model be at least the following:

- For Medicare QP Performance Period 2018, 2 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.
- For Medicare QP Performance Period 2019, 3 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.
- For Medicare QP Performance Period 2020, 4 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.
- For Medicare QP Performance Periods 2021 and later, 5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

We seek comment on this proposal.

c. Summary of Proposals

In summary, we are making the following proposals in this section:

- We are proposing to amend our regulation at § 414.1415(c)(3)(i)(A) and (c)(4)(i)(A) through (D) to more clearly define the generally applicable revenue-based nominal amount standard and the Medical Home Model revenue-based nominal amount standard as a percentage of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.
- We are proposing to amend our regulation at § 414.1415(c)(2) to any APM Entities enrolled in an Advanced APM qualifying under the Medical Home Model standard as of January 1, 2017, to exempt Round 1 of the CPC+ Model from the requirement that beginning in the 2018 Medicare QP Performance Period, the Medical Home Model financial risk standard applies only to an APM Entity that is participating in a Medical Home Model if it has fewer than 50 eligible clinicians in its parent organization.
- We are proposing to amend our regulation at § 414.1415(c)(3)(i)(A) to provide that the generally applicable revenue-based nominal amount standard remain at 8 percent of the average estimated total Medicare Parts A and B revenue of providers and suppliers in participating APM Entities for the 2019 and 2020 Medicare QP Performance Periods, and to address the standard for Medicare QP Performance Periods after 2020 through subsequent rulemaking.

• We are proposing to amend our regulation at § 414.1415(c)(4)(i)(A) through (D) to provide that, to be an Advanced APM, a Medical Home Model must require that the total annual amount that an APM Entity potentially owes us or foregoes under the Medical Home Model be at least the following amounts:

++ For Medicare QP Performance Period 2018, 2 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

++ For Medicare QP Performance Period 2019, 3 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

++ For Medicare QP Performance Period 2020, 4 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

++ For Medicare QP Performance Periods 2021 and later, 5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

5. Qualifying APM Participant (QP) and Partial QP Determination

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (See 81 FR 77433 through 77450).

We finalized that the QP Performance Period will run from January 1 through August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446). As we discuss in section II.D.6.(d)(2)(a)of this proposed rule, we propose to refer to this time period for the Medicare Option as the Medicare QP Performance Period.

a. Advanced APMs Starting or Ending During a Medicare QP Performance Period

We acknowledge that there may be Advanced APMs that start after January 1 of the Medicare QP Performance Period for a year. There may also be Advanced APMs that end prior to the August 31 end of the Medicare QP Performance Period for a year. By ''start'' and ''end,'' in this context, we mean that the period of active testing of the model starts or ends such that there is no opportunity for any APM Entity to participate in the Advanced APM before it starts, or to participate in it after it ends. We consider the active testing period to mean the dates within the performance period specific to the model, which is also the time period for which we consider payment amounts or patient counts through the Advanced APM when we make QP determinations. An Advanced APM is in active testing if APM Entities are furnishing services to beneficiaries and those services will count toward the APM Entity's performance in the Advanced APM. Active testing does not include, for example, the period of time after an APM Entity has stopped furnishing services to beneficiaries under the terms of the Advanced APM but is waiting for calculation or receipt of a performance-based payment. We note that we tie this policy to the timeframe during which APM Entities, rather than eligible clinicians, participate in an Advanced APM. To the extent the participation of APM Entities and eligible clinicians is not the same, we believe it is more appropriate and consistent with other policies relating to the APM incentive, and to APMs in general, to base the active testing period for an APM on the activities of the APM Entities because they are the participants directly subject to the terms of the Advanced APM, including the specified performance period for the Advanced APM. For example, in a model like CJR, where we identify eligible clinicians for QP determinations based on the Affiliated Practitioner List, it would be possible for APM Entities to be participating in active testing of the Advanced APM without any Affiliated Practitioners for a period of time. In that case, we would consider the dates the APM Entities were able to be in active testing for CJR, as opposed to the dates when eligible clinicians began participating as Affiliated Practitioners. If a specific APM Entity joins an Advanced APM after the January 1 start and before the August 31 end of a Medicare QP Performance Period, but other APM Entities participate during the entire Medicare QP Performance Period (from January 1 through August 31), then we would consider the Advanced APM to be in active testing for the entire Medicare QP Performance Period.

For example, the performance period for an Advanced APM may start on May 1, which is after the first QP determination date (March 31) and before the second QP determination date (June 30) during the Medicare QP Performance Period. If we were to calculate Threshold Scores in such an Advanced APM using data in the denominator for all attribution-eligible beneficiaries from January through June 30, which would include data for the period before the Advanced APM is actively tested, the APM Entities, or, as applicable, individual eligible clinicians in that Advanced APM, are less likely to achieve a QP threshold on either the June 30 or the final August 31 determination date for the year. This outcome would be a direct result of our operational decisions to begin the performance period for the Advanced APM on May 1, which is outside of the control of both the participating APM Entities and eligible clinicians. As such, participants in Advanced APMs that start or end during the Medicare QP Performance Period for the year could be disadvantaged for purposes of QP determinations. This is because the numerator of the Threshold Score calculation would include payment amounts or patient counts from only the period before the QP determination date during which the Advanced APM was actively tested, while the denominator would include payment amounts or patient counts for the entire Medicare QP performance period up to the QP determination date.

We propose to modify our policies regarding the timeframe(s) for which payment amount and patient count data are included in the QP payment amount and patient count threshold calculations for Advanced APMs that start after January 1 or end before August 31 in a given Medicare QP Performance Period. In these situations, we would calculate QP Threshold Scores using only data in the numerator and denominator for the dates that APM Entities were able to participate in active testing of the Advanced APM, per the terms of the Advanced APM, so long as APM Entities were able to participate in the Advanced APM for 60 or more continuous days during the Medicare QP Performance Period. We propose to add this policy at § 414.1425(c)(6) of our regulations. The QP Threshold Score would be calculated at the APM Entity level or the Affiliated Practitioner level as set forth in § 414.1425(b); this change would not affect our established policy as to which list of eligible clinicians, the Participation List or Affiliated Practitioner List, would be used.

This proposed change would not affect how we make QP and Partial QP determinations for eligible clinicians who participate in multiple Advanced APMs as set forth by §§ 414.1425(c)(4) and 414.1425(d)(2). We propose to make those calculations using the full Medicare QP Performance Period even if the eligible clinician participates in one or more Advanced APMs that start or end during the Medicare QP Performance Period. We believe that this policy appropriately reflects the participation of the individual eligible clinician in multiple Advanced APMs and is consistent with our general framework for making QP determinations. For these QP determinations, we would include

patients or payments through all Advanced APMs the eligible clinician participates in for a Medicare QP Performance Period, including any Advanced APMs that are in active testing for less than 60 continuous days. This policy accounts for the eligible clinician's flexibility in participating in Advanced APMs while combining that participation to potentially meet the QP threshold.

With the exception of QP determinations for individual eligible clinicians who participate in multiple Advanced APMs, we believe it is appropriate to require that an Advanced APM must be actively tested for a minimum of 60 continuous days during the Medicare QP Performance Period in order for the payment amount or patient count data to be considered for purposes of QP determinations for the year because it is important that the QP determination be based on a measure of meaningful participation in an Advanced APM. For example, if an Advanced APM started on August 30, we do not believe a QP determination made based on only 2 days of payment amount or patient count data in the numerator and denominator would reflect a meaningful assessment of participation in an Advanced APM. We have chosen a minimum of 60 continuous days because it is the shortest amount of time between two snapshot dates: June 30 and August 31. We believe this amount of time is sufficient for purposes of measuring participation in an Advanced APM. We seek comment on whether it would be more appropriate to require that the Advanced APM be in active testing for at least 90 days, since 90 days is the shortest possible length of time we would use to make a QP determination (if the QP determination is based on January 1 through March 31).

Under this proposal, we would make QP determinations for all QP determination snapshot dates that fall after the Advanced APM meets the minimum time requirement of 60 continuous days, whether the Advanced APM starts or ends during the Medicare QP Performance Period. We would not make a QP or Partial QP determination for participants in Advanced APMs that are not actively tested for a period of at least 60 continuous days during the Medicare QP Performance Period. For example, for an Advanced APM that starts its performance period on June 1, we would not make any QP Threshold Score calculations for the June 30 snapshot date because the Advanced APM would not yet have been actively tested for 60 consecutive days. We would wait until the August 31 snapshot date because this would be the first snapshot where the Advanced APM was active for 60 or more continuous days. The QP determination would be made based on payment amounts or patient counts from the June 1 start date to August 31 in both the numerator and the denominator. For an Advanced APM that starts on or before January 1 and ends active testing on June 1, we would make QP determinations on each snapshot date, but those determinations would be made based only on payment amounts or patient counts from January 1 to June 1. Although the Advanced APM would not be actively tested between June 30 and August 31, we would still make another QP Threshold Score calculation for APM Entities or eligible clinicians who had not met the QP Threshold in case the additional time for claims run out would give us more accurate information. For an Advanced APM that started on August 30 of a year, we would not make a QP determination for that year because the APM would not be actively tested for 60 continuous days during the Medicare QP Performance Period.

We believe that this proposal allows us to properly measure performance in Advanced APMs without penalizing APM Entities or eligible clinicians for start or end dates that are wholly outside of their control. We believe this policy is needed to match the data used to assess Advanced APM participation for purposes of the APM incentive payment with the timeframe during which the Advanced APM is actively tested and to accurately reflect the participation of APM Entities and eligible clinicians. This proposed policy would not apply to Other Payer Advanced APMs because eligible clinicians have more control over the start and end dates of payment arrangements with Other Payers, such as through contract negotiations, than they do over our start and end dates, which we exclusively determine.

This proposed policy would not apply to APM Entities that had the opportunity to participate in the Advanced APM track of an APM during the entire Medicare QP Performance Period, but did not do so until partway through the Medicare QP Performance Period. For example, Oncology Care Model (OCM), has two risk tracks: One-sided and two-sided risk. Only the two-sided risk track is an Advanced APM. APM Entities participating in OCM now have the opportunity to change their risk track from one-sided to two-sided risk, to take effect on either January 1 or July 1 of the applicable calendar year. Applying this proposed policy to OCM, an APM Entity participating in OCM that requests two-sided risk to take effect beginning on July 1, 2018, would be considered a participant in and Advanced APM as of July 1, but would be subject to a QP determination based on payment and patient count data for the full Medicare QP Performance Period because that APM Entity had the opportunity to elect two-sided risk beginning on January 1, 2018. In this scenario, the APM Entity has control over its participation in an Advanced APM, and could choose to be in the Advanced APM for the full Medicare QP Performance Period.

We clarify that this proposed policy for Advanced APMs that start or end during the Medicare QP Performance Period does not apply to the CEHRT Track (Track 1) of the Comprehensive Care for Joint Replacement Model (CJR) because we have determined that Track 1 of CJR is an Advanced APM for the 2017 QP Performance Period. Therefore, we will include episodes ending on or after January 1, 2017 in QP determinations as set forth in our regulations at § 414.1425.

b. Participation in Multiple Advanced APMs

We propose to edit § 414.1425(c)(4) and (d)(4) to better reflect our intended policy for QP determinations and Partial QP determinations for eligible clinicians who are included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or who are Affiliated Practitioners. As we explained in the CY 2017 Quality Payment Program final rule (81 FR 77446–7), eligible clinicians may become QPs through any of the assessments conducted for the three snapshot dates: March 31, June 30, and August 31. If the APM Entity group meets the QP threshold under this first assessment, then all eligible clinicians in the APM Entity group will be QPs unless the APM Entity's participation in the Advanced APM is voluntarily or involuntarily terminated before the end of the Medicare QP Performance Period, or in the event of eligible clinician or APM Entity program integrity violation. We stated these same procedures apply to the QP determination made for individual eligible clinicians on an APM Entity's Affiliated Practitioner List or individual eligible clinicians in multiple Advanced APMs whose APM Entity groups did not meet the QP threshold.

We propose to amend our regulation to make clear that under § 414.1425(c)(4), if an eligible clinician is a determined to be a QP based on

participation in multiple Advanced APMs, but any of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the Medicare QP Performance Period, the eligible clinician is not a QP. We propose to make the same clarification for Partial QP determinations under § 414.1425(d)(4). These clarifying edits specify that this policy applies within the context of QP and Partial QP determinations based on participation in multiple Advanced APMs, not all QP determinations. Accordingly, for example, if an eligible clinician is a QP through participation in both of two Advanced APMs under § 414.1425(b)(1), and one APM Entity voluntarily or involuntarily terminates from one of those Advanced APMs, the eligible clinician is still a QP. However, if the eligible clinician is a QP through participation in multiple Advanced APMs under § 414.1425(c)(4), and any APM Entity that eligible clinician participates in that counts towards the QP determination voluntarily or involuntarily terminates, the eligible clinician is no longer a QP. We seek comment on these proposals.

c. Summary of Proposals

In summary, we are making the following proposals in this section:

- We propose to calculate QP Threshold Scores for Advanced APMs that are actively tested continuously for a minimum of 60 days during the Medicare QP Performance Period and start or end during the Medicare QP Performance Period using only the dates that APM Entities were able to participate in the Advanced APM per the terms of the Advanced APM, not the full Medicare QP Performance Period.
- We propose to make QP determinations under § 414.1425(c)(4), for eligible clinicians participating in multiple Advanced APMs using the full Medicare QP Performance Period even if the eligible clinician participates in one or more Advanced APMs that start or end during the Medicare QP Performance Period.
- We propose to amend our regulation to make clear that under § 414.1425(c)(4), if an eligible clinician is determined to be a QP based on participation in multiple Advanced APMs, but any of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the Medicare QP Performance Period, the eligible clinician is not a QP.

6. All-Payer Combination Option

a. Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule (81 FR 77459), we finalized our overall approach to the All-Payer Combination Option. The Medicare Option focuses on participation in Advanced APMs, and we make determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it would allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess Medicare Part B covered professional services furnished through Advanced APMs, and a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). An eligible clinician only needs to be a QP under either the Medicare Option or the All-Payer Combination Option to be a QP for the payment year. The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements with payers other than Medicare that have payment designs that satisfy the Other Payer Advanced APM criteria. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 46, 47, and Figures K1 and K2 (See 81 FR 77460 through 77461). We also finalized that, in making QP determinations, we will use the Threshold Score that is most advantageous to the eligible clinician toward achieving QP status for the year, or if QP status is not achieved, Partial QP status for the year (81 FR 77475).

TABLE 46: QP Payment Amount Thresholds – All-Payer Combination Option

All-Payer Combination Option – Payment Amount Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Payment Amount Threshold	N/A	N/A	50%	25%	50%	25%	75%	25%	75%	25%
Partial QP Payment Amount Threshold	N/A	N/A	40%	20%	40%	20%	50%	20%	50%	20%
			Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

TABLE 47: QP Patient Count Thresholds – All-Payer Combination Option

All-Payer Combination Option – Patient Count Method										
Payment Year	**2019**	**2020**	**2021**		**2022**		**2023**		**2024 and later**	
QP Patient Count Threshold	N/A	N/A	35%	20%	35%	20%	50%	20%	50%	20%
Partial QP Patient Count Threshold	N/A	N/A	25%	10%	25%	10%	35%	10%	35%	10%
			Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

FIGURE 1: QP Determination Tree, Payment Years 2021-2022

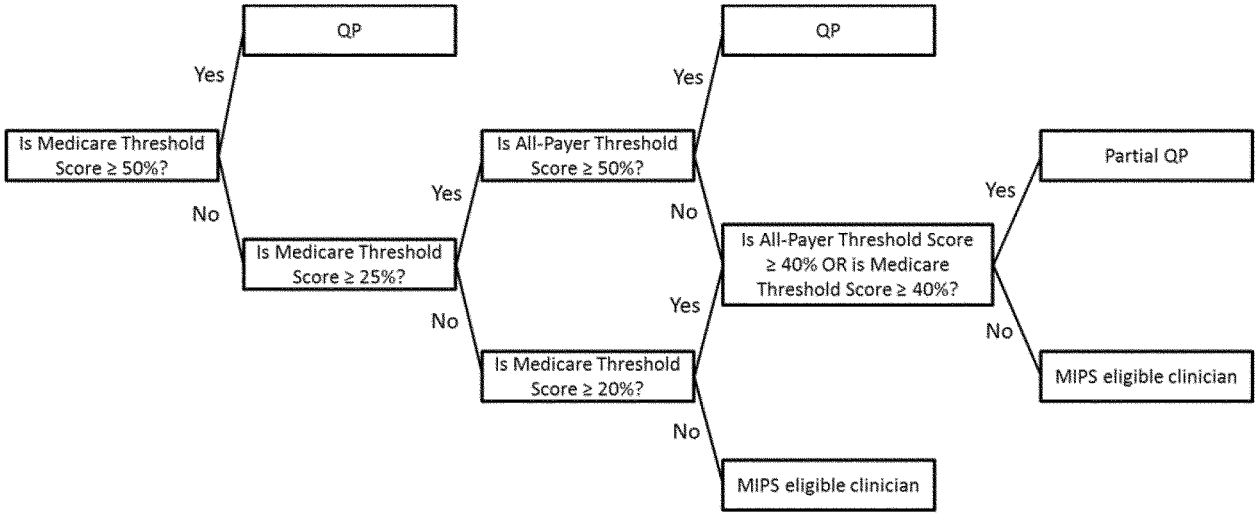
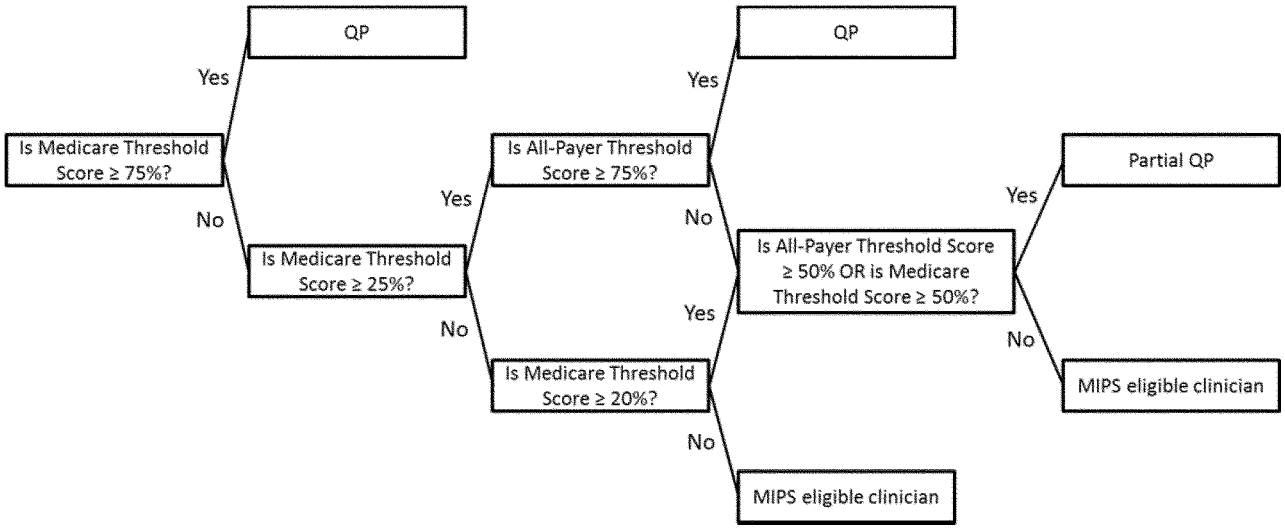


FIGURE 2: QP Determination Tree, Payment Years 2023 and Later



Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot identify whether an other payer arrangement meets the criteria to be an Other Payer Advanced APM without receiving the required information from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving the required information from an external source.

We finalized the process that eligible clinicians can use to seek a QP determination under the All-Payer Combination Option (81 FR 77478 through 77480):

- The eligible clinician submits to CMS sufficient information on all relevant payment arrangements with other payers;
- Based upon that information CMS determines that at least one of those payment arrangements is an Other Payer Advanced APM; and
- The eligible clinician meets the relevant QP thresholds by having sufficient payments or patients attributed to a combination of participation in Other Payer Advanced APMs and Advanced APMs.

We address the following topics in this section of the proposed rule: (1) Other Payer Advanced APM Criteria; (2) Determination of Other Payer Advanced APMs; and (3) Calculation of All-Payer Combination Option Threshold Scores and QP Determinations.

b. Other Payer Advanced APM Criteria

(1) In General

Our goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We believe this alignment will help simplify the Quality Payment Program and encourage participation in Other Payer Advanced APMs.

In the CY 2017 Quality Payment Program final rule, we finalized that, in general, an other payer arrangement with any payer other than traditional Medicare, including Medicare Health Plans, which include Medicare Advantage, Medicaid-Medicaid Plans, 1876 and 1833 Cost Plans, and Programs of All Inclusive Care for the Elderly (PACE) plans, will be an Other Payer Advanced APM if it meets all three of the following criteria:

- The other payer arrangement requires at least 50 percent of participating eligible clinicians in each APM Entity (or each hospital if hospitals are the APM participants) to use Certified EHR Technology (CEHRT) to document and communicate clinical care (81 FR 77464 through 77465);
- The other payer arrangement requires that quality measures comparable to measures under the MIPS quality performance category apply, which means measures that are evidence-based, reliable and valid; and, if available, at least one measure must be an outcome measure (81 FR 77466); and
- The other payer arrangement either: (1) Requires APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures (under either the generally applicable or Medicaid Medical Home Model standards for nominal amount of financial risk, as applicable); or (2) is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act (81 FR 77466 through 77467).

(2) Other Payer Medical Home Models

In the CY 2017 Quality Payment Program final rule we finalized definitions of Medical Home Model and Medicaid Medical Home Model at § 414.1305. The statute does not define ''medical homes,'' but sections 1848(q)(5)(C)(i), 1833(z)(2)(B)(iii)(II)(cc)(BB), 1833(z)(2)(C)(iii)(II)(cc)(BB), and 1833(z)(3)(D)(ii)(II) of the Act make medical homes an instrumental piece of the Quality Payment Program.

We recognize that there may be medical homes that are operated by other payers that may be appropriately considered medical home models under the All-Payer Combination Option. Examples of these arrangements may include those aligned with the Comprehensive Primary Care Plus (CPC+) model. Therefore, we seek comment on whether we should define the term Other Payer Medical Home Model as an other payer arrangement that is determined by CMS to have the following characteristics:

- The other payer arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;
- Empanelment of each patient to a primary clinician; and
- At least four of the following:

++ Planned coordination of chronic and preventive care.

++ Patient access and continuity of care.

++ Risk-stratified care management.

++ Coordination of care across the medical neighborhood.

++ Patient and caregiver engagement.

++ Shared decision-making.

++ Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

Similar to Medical Home Models and Medicaid Medical Home Models, we believe that Other Payer Medical Home Models could be considered unique types of other payer arrangements for purposes of the Quality Payment Program. We anticipate that participants in these arrangements may generally be more limited in their ability to bear financial risk than other entities because they may be smaller and predominantly include primary care practitioners, whose revenues are a smaller fraction of the patients' total cost of care than those of other eligible clinicians. Because of these factors, we believe it may be appropriate to determine whether an Other Payer Medical Home Model satisfies the financial risk criterion by using special Other Payer Medical Home Model financial risk and nominal amount standards, which could be different from the generally applicable Other Payer Advanced APM standards and would be identical to the Medicaid Medical Home Model financial risk and nominal amount standards.

We are particularly interested in, and seek comment on, whether there are payment arrangements that currently exist that would meet this definition. We encourage commenters to note whether such payment arrangements would meet the existing generally applicable Other Payer Advanced APM financial risk and nominal amount standards. We also request comments on any special considerations that might be relevant when establishing a definition for a medical home model standard for payers with payment arrangements that would not fit under the Medical Home Model or Medicaid Medical Home Model definitions, including how the 50 clinician cap discussed in section II.D.4.b.(1) of this proposed rule for the Medical Home Model nominal amount standard would apply.

(3) Financial Risk for Monetary Losses

In the CY 2017 Quality Payment Program final rule we finalized policies to assess whether an other payer arrangement requires participating APM Entities to bear more than nominal financial risk if aggregate expenditures exceed expected aggregated expenditures (more than nominal financial risk for monetary losses). This Other Payer Advanced APM criterion has two components: A financial risk standard and a nominal amount standard. The financial risk standard defines what it means for an APM Entity to bear financial risk if actual aggregate expenditures exceed expected aggregate expenditures under an other payer arrangement. We finalized a generally applicable financial risk standard and a Medicaid Medical Home Model financial risk standard for Other Payer Advanced APMs. (See 81 FR 77466 through 77474).

We finalized that for an other payer arrangement to meet the generally applicable financial risk standard for Other Payer Advanced APMs, if an APM Entity's actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period, the payer must:

- Withhold payment of services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to APM Entity and/or the APM Entity's eligible clinicians; or
- Require direct payments by the APM Entity to the payer (81 FR 77467).

We also finalized that for a Medicaid Medical Home Model to be an Other Payer Advanced APM, if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period, the Medicaid Medical Home Model must:

- Withhold payment of services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to APM Entity and/or the APM Entity's eligible clinicians;
- Require direct payments by the APM Entity to the payer; or
- Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments (81 FR 77468 through 77469).

(a) Generally Applicable Nominal Amount Standard

(i) Marginal Risk and Minimum Loss Rate

The generally applicable nominal amount standard that we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77471) for Other Payer Advanced APMs differs from the generally applicable nominal amount standard for Advanced APMs in two ways.

First, the finalized generally applicable Advanced APM nominal amount standard only requires an APM to meet one measure of risk—total risk (81 FR 77424). The finalized generally applicable Other Payer Advanced APM nominal amount standard involves assessment of the following three measures of risk:

- Marginal risk—the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the payment arrangement.
- Minimum loss rate—a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk.
- Total risk—the maximum potential payment for which an APM Entity could be liable under a payment arrangement.

We note that as described in the CY 2017 Quality Payment Program final rule (81 FR 77426), although we did not formally adopt marginal risk or minimum loss rate criteria for Advanced APMs, we pointed out that all current Advanced APMs would meet these standards, and that we intend that all future Advanced APMs would meet the three measures of risk as well. Therefore, we do not expect the application of the different criteria between Advanced APMs and Other Payer Advanced APMs to produce meaningfully different results in terms of actual risk faced by participants.

Second, the finalized generally applicable Advanced APM nominal amount standard allows for total risk to be defined in one of two ways, based on expected expenditures (the benchmark-based standard) or based on revenue (the revenue-based standard) (81 FR 77427). In contrast, the finalized Other Payer Advanced APM generally applicable nominal amount standard is only based on expected expenditures (81 FR 77471).

In the CY 2017 Quality Payment program final rule, we sought comments on using the expected expenditures approach for the generally applicable Other Payer Advanced APM nominal amount standard.

Table 48 lists the requirements of the generally applicable nominal amount standards as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77427 and 77471).

TABLE 48—GENERALLY APPLICABLE NOMINAL AMOUNT STANDARDS FOR ADVANCED APMS AND OTHER PAYER ADVANCED APMS FINALIZED IN THE CY 2017 QUALITY PAYMENT PROGRAM FINAL RULE

	Advanced APMs	Other Payer Advanced APMs
Generally Applicable Nominal Amount Standard	For 2017 and 2018, nominal amount of risk must be at least equal to either: • 8 percent of average estimated total of Medicare Part A and Part B revenues of all providers and suppliers in participating APM Entities; or. • 3 percent of expected expenditures for which the APM entity is responsible.	Nominal amount of risk must be: • Marginal Risk of at least 30 percent; • Minimum Loss Rate of no more than 4 percent; and • Total Risk of at least 3 percent of the expected expenditures for which the APM Entity is responsible.

We do not propose to modify the marginal risk and minimum loss rate requirements as we finalized in the CY 2017 Quality Payment Program final rule as part of the generally applicable nominal amount standard for Other Payer Advanced APMs. We continue to believe that using these measures of risk will ensure that payment arrangements involving other payers and APM Entities or eligible clinicians cannot be engineered in such a way as to provide eligible clinicians an avenue to QP status through an Other Payer Advanced APM that technically meets the financial risk criterion but carries a very low risk of losses based on performance. Because we do not have direct control over the design of Other Payer Advanced APMs, we believe the use of a multi-factor nominal amount standard to assess financial risk provides greater assurance that Other Payer Advanced APMs will involve true financial risk in accordance with statutory requirements. Including marginal risk and a minimal loss rate as components of the nominal amount standard assures that the payment arrangements that we could determine are Other Payer Advanced APMs and could contribute to the attainment of QP status are similarly rigorous to Advanced APMs. We request additional comments on this approach, and on whether there are potential alternative approaches to achieving these goals.

(ii) Revenue-Based Generally Applicable Nominal Amount Standard

We propose to add a revenue-based nominal amount standard to the generally applicable nominal amount standard for Other Payer Advanced APMs that is parallel to the revenue-based nominal amount standard for Advanced APMs. Specifically, we propose that an other payer arrangement would meet the revenue-based nominal amount standard we are proposing if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: For the 2019 and 2020 All-Payer QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities. We would use this standard for other payer arrangements where financial risk is expressly defined in terms of revenue in the payment arrangement. We seek comment on this proposal.

For Advanced APMs, we may determine that an APM still meets the

revenue-based generally applicable nominal amount standard, even if risk is not explicitly defined in terms of revenue, by comparing model downside risk to the estimated average Medicare revenue of model participants. Because we have direct access to Medicare claims data, we can estimate such an average. For other payers, we do not have similar direct access to claims data. As such, there are significant operational challenges to identifying whether an other payer arrangement would satisfy the revenue-based nominal amount standard when the other payer arrangement does not define risk explicitly in terms of revenue. We do not have direct access to other payer revenue data, so we could not do this calculation without significant assistance from the relevant payer. For this reason, we propose that the revenue-based standard would only be applied to other payer arrangements in which risk is explicitly defined in terms of revenue, as specified in an agreement covering the other payer arrangement.

We propose that under the generally applicable nominal amount standard for Other Payer Advanced APMs, an other payer arrangement would need to meet either the benchmark-based nominal amount standard or the revenue-based nominal amount standard, and need not meet both. We believe this proposed approach to the nominal amount standard would expand the opportunities for other payer arrangements to meet the generally applicable nominal amount standard, and would allow closer alignment between Medicare and other payers as new payment arrangements are introduced and evolve. As with the revenue-based nominal amount standard for Advanced APMs, which we discuss in section II.D.4.b.(2)(a) of this proposed rule, we seek comment on whether we should consider either a lower or higher revenue-based nominal amount standard for the 2019 and 2020 All-Payer QP Performance Periods, and on the amount and structure of the revenue-based nominal amount standard for All-Payer QP Performance Periods 2021 and later.

We also seek comment on whether we should consider a different, potentially lower, revenue-based nominal amount standard only for small practices and those in rural areas that are not participating in a Medicaid Medical Home Model for the 2019 and 2020 All-Payer QP Performance Periods. For the purposes of the Quality Payment Program, we use the definition of small practices and rural areas in § 414.1305. We believe that a different, potentially lower, revenue-based nominal amount standard for the 2019 and 2020 All-Payer QP Performance Periods specifically for small and rural organizations may allow for their increased participation in Advanced APMs, which may help increase the quality and coordination of care beneficiaries receive as a result. Specifically, we seek comment on whether such a standard should apply only to small and, or, rural practices that are participants in an APM, or also to small and/or rural practices that join larger APM Entities to participate in APMs. We also seek comment on how we should decide where a practice is located to determine whether it is operating in a rural area is defined in § 414.1305.

(b) Medicaid Medical Home Model Nominal Amount Standard

In the CY 2017 Quality Payment Program final rule (81 FR 77472), in addition to the financial risk standard for Medicaid Medical Home Models, we finalized that to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that an APM Entity potentially owes or foregoes be at least the following amounts in a given performance year:

- In 2019, 4 percent of the APM Entity's total revenues under the payer.
- In 2020 and later, 5 percent of the APM Entity's total revenues under the payer.

Table 49 lists the requirements of the Medicaid Medical Home Model nominal amount standards as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77428 and 77472).

TABLE 49—MEDICAID MEDICAL HOME MODEL NOMINAL AMOUNT STANDARDS FOR ADVANCED APMS AND OTHER PAYER ADVANCED APMS FINALIZED IN THE CY 2017 QUALITY PAYMENT PROGRAM FINAL RULE

	Medical Home Model	Medicaid Medical Home Model
Nominal Amount Standard	Nominal amount of risk must be: • In 2017, 2.5 percent • In 2018, 3 percent • In 2019, 4 percent • In 2020 and later, 5 percent	Nominal amount of risk must be: • In 2019, 4 percent. • In 2020 and later, 5 percent.

As we have discussed in section II.D.4.b.(2)(b) of this proposed rule regarding APM Entities in Medical Home Models, we have also received comments that few APM Entities in Medical Home Models and Medicaid Medical Home Models have had experience with financial risk, and that many would be financially challenged to provide sufficient care or even remain a viable business in the event of substantial disruptions in revenue. We understand these concerns that the gradual increase in risk over time may be unmanageable for some APM Entities; however, we still believe that a final Medicaid Medical Home Model nominal amount standard of 5 percent is appropriate and that setting the standard at 5 percent of the APM Entity's total revenue under the payer appropriately reflects the meaning of nominal in the Medicaid Medical Home Model context.

We have reconsidered the incremental annual increases in the standard over several years. Our policy finalized in the CY 2017 Quality Payment Program final rule set forth what we envisioned was a gradually increasing but achievable amount of risk that would apply over time. In general, we still believe this to be true, but recognize that establishing an even more gradual increase in risk for Medicaid Medical Home Models may better suit many APM Entities in Medicaid Medical Home Models that have little experience with risk. To that end, we believe a small reduction of risk in the Medicaid Medical Home Model nominal amount standard beginning in the 2019 All-Payer QP Performance Period may allow for greater flexibility in setting financial risk thresholds that would encourage more participation in Medicaid Medical Home Models and be more sustainable for the type of APM Entities that would potentially participate in Medicaid Medical Home Models.

Therefore, we are proposing that, to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that

an APM Entity potentially owes or foregoes under the Medicaid Medical Home Model must be at least:

- For All-Payer QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.
- For All-Payer QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.
- For All-Payer QP Performance Period 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

We seek comment on this proposal.

(4) Summary of Proposals

In summary, we are proposing the following:

- We propose that an other payer arrangement would meet the revenue-based nominal amount standard we are proposing if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: for the 2019 and 2020 All-Payer QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities.
- We are proposing that to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that an APM Entity potentially owes or foregoes under the Medicaid Medical Home Model must be at least:

++ For All-Payer QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.

++ For All-Payer QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.

++ For All-Payer QP Performance Period 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

c. Determination of Other Payer Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule, we established a prospective Advanced APM determination process (81 FR 77408). This prospective approach was implemented to ensure that APM Entities and eligible clinicians were aware of which APMs met the Advanced APM criteria prior to the first QP Performance Period, and because we have a general goal of providing notice, when possible, of which models are Advanced APMs prior to the beginning of the Medicare QP Performance Period. We were able to perform Advanced APM determinations within the time period between the effective date of the CY 2017 Quality Payment Program final rule and the beginning of the first QP Performance Period because we already possessed all of the information necessary.

For other payer arrangements, we specified that an APM Entity or eligible clinician must submit, by a date and in a manner determined by us, information necessary to identify whether a given payment arrangement satisfies the Other Payer Advanced APM criteria (81 FR 77480). We finalized that we will identify Medicaid APMs and Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria before the beginning of the QP Performance Period (81 FR 77478 through 77480). We also sought comment on the overall process for reviewing payment arrangements to determine whether they are Other Payer Advanced APMs, and we also sought comment on whether we should create a separate pathway to identify whether other payer arrangements with Medicaid as a payer meet the Other Payer Advanced APM criteria (81 FR 77463).

(a) Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process)

We propose to allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements in CMS Multi-Payer Models to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 All-Payer QP Performance Period and each year thereafter. We propose to generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process). We believe that establishing this Payer Initiated Process would be beneficial to APM Entities and eligible clinicians because it would help reduce their reporting burden, and it would provide us with the most complete information on payment arrangements. In addition, we believe the Other Payer Advanced APM determinations made via the Payer Initiated Process could be completed prior to the All-Payer QP Performance Period, and we could therefore provide APM Entities and eligible clinicians with information that may help them plan their participation in Other Payer Advanced APMs.

When referring to Medicare Health Plans in the context of the Payer Initiated Process, we include in the term Medicare Advantage and certain types of plans including Medicare-Medicaid Plans, 1876 and 1833 Cost Plans, and Programs of All Inclusive Care for the Elderly (PACE) Plans.

If a payer requests that we determine whether a payment arrangement authorized under Title XIX, a Medicare Health Plan payment arrangement, or a payment arrangement in a CMS Multi-Payer Model is an Other Payer Advanced APM, and the payer uses the same other payer arrangement in other commercial lines of business, we propose to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well. We will make Other Payer Advanced APM determinations for each individual payment arrangement.

We propose that these Other Payer Advanced APM determinations would be in effect for only one year at a time. Payers would need to submit payment arrangement information each year in order for us to make an Other Payer Advanced APM determination in each year. We believe this approach is appropriate since payment arrangements can change from year to year, and also since we may modify aspects of the Other Payer Advanced APM criteria from one year to the next. We seek comment on this approach, and we are exploring ways to streamline this process over time.

We propose to allow remaining other payers, including commercial and other private payers, to request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 All-Payer QP Performance Period and annually each year thereafter. We believe that phasing in the Payer Initiated Process would allow us to gain experience with the determination process on a limited basis with payers where we have the strongest relationships and existing processes that we believe can help facilitate submitting this information. We anticipate making improvements and refinements to this process, which we believe will help us facilitate receiving this information from the remaining other payers.

We propose that the Payer Initiated Process would be voluntary for all payers. We propose that the Payer Initiated Process would generally involve the same steps for each payer type as listed below for each All-Payer QP Performance Period, and we elaborate on details within this framework that are specific to payer type in the following subsections:

Guidance and Submission Form: We intend to make guidance available regarding the Payer Initiated Process for each payer type prior to the first Submission Period, which would occur

during 2018. We intend to develop a submission form (which we refer to as the Payer Initiated Submission Form) that would be used by payers to request Other Payer Advanced APM determinations, and we intend to make this Payer Initiated Submission Form available to payers prior to the first Submission Period. We propose that payers would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all payment arrangements and some that are specific to a particular type of payment arrangements, and we intend for it to include a way for payers to attach supporting documentation. We propose that payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that the Submission Period opening date and Submission Deadline would vary by payer type to align with existing CMS processes for payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements in CMS Multi-Payer Models to the extent possible and appropriate. We are proposing these dates based on operational timelines that take into account the time necessary to review submitted information, to align with other relevant deadlines in the Quality Payment Program to the extent possible, and to provide payers with as much notice of what is required in the Payer Initiated Process and as much time to complete any Payer Initiated Submission Form as possible.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the payer has submitted incomplete or inadequate information, we would inform the payer and allow the payer to submit additional information no later than 10 business days from the date we inform the payer. For each other payer arrangement for which the payer does not submit sufficient information, we would not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We intend to notify payers of our determinations for each request as soon as practicable after the relevant Submission Deadline. APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

We believe that this proposed Payer Initiated Process would encourage greater participation in Other Payer Advanced APMs, particularly because it would allow us to post a list of at least some of the Other Payer Advanced APMs before the start of the All-Payer QP Performance Period as discussed in section II.D.6.d.(2)(a) of this proposed rule. We also believe that payers are well positioned to compile and submit to us the information we require to make Other Payer Advanced APM determinations because they develop other payer arrangements. We seek comment on these proposals.

We note that we will seek OMB approval for the proposed Payer Initiated Submission Form separately from this rulemaking process. In accordance with the Paperwork Reduction Act (PRA), we will publish the required 60-day public notice and 30-day public notice. In addition, the entire information collection request and all associated forms will be made available for public review prior to OMB submission.

(b) APM Entity or Eligible Clinician Initiated Other Payer Advanced APM Determination Process (Eligible Clinician Initiated Process)

In the CY 2017 Quality Payment Program final rule, we finalized that APM Entities and eligible clinicians in payment arrangements with other payers would have an opportunity to request determinations of whether an other payer arrangement(s) is an Other Payer Advanced APM after the QP Performance Period (81 FR 77480). At that time, APM Entities and eligible clinicians would know which payment arrangements they participated in during the preceding QP Performance Period. We clarify that both APM Entities and eligible clinicians may request Other Payer Advanced APM determinations through this process, and we refer to this process as the Eligible Clinician Initiated Process.

We propose that through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process could also be used to request determinations before the beginning of an All-Payer QP Performance Period for other payer arrangements authorized under Title XIX, as we discuss in section II.D.6.(c)(2)(b) of this proposed rule. The Eligible Clinician Initiated Process would not be necessary for, or applicable to, other payer arrangements that are already determined to be Other Payer Advanced APMs through the Payer Initiated Process.

Guidance and Submission Form: We intend to make guidance available regarding the Eligible Clinician Initiated Process for each payer type prior to the first Submission Period, which would occur during 2018. We intend to develop a submission form (which we refer to as the Eligible Clinician Initiated Submission Form) that would be used by APM Entities or eligible clinicians to request Other Payer Advanced APM determinations, and we intend to make this Eligible Clinician Initiated Submission Form available to APM Entities and eligible clinicians prior to the first Submission Period. We propose that APM Entities and eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Eligible Clinician Initiated Submission Form to include

questions that are applicable to all other payer arrangements and some that are specific to a particular type of other payer arrangements, and we intend for it to include a way for APM Entities or eligible clinicians to attach supporting documentation. We propose that APM Entities or eligible clinicians may submit requests for review of multiple other payer arrangements through the Eligible Clinician Initiated Process, though we would make separate determinations as to each other payer arrangement, and an APM Entity or eligible clinician would be required to use a separate Eligible Clinician Initiated Submission Form for each other payer arrangement. APM Entities or eligible clinicians may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: In general, we propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We discuss our proposal to establish the All-Payer QP Performance Period in section II.D.6.d.(2)(a) of this proposed rule. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

CMS Determination: Upon timely receipt of an Eligible Clinician Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that, if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the APM Entity or eligible clinician and allow the APM Entity or eligible clinician to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify APM Entities and eligible clinicians of our determinations for each other payer arrangement for which a determination was requested as soon as practicable after the Submission Deadline.

We note that APM Entities and eligible clinicians who submit complete Eligible Clinician Initiated Submission Forms by September 1 of the calendar year of the relevant All-Payer QP Performance Period may allow for us to make Other Payer Advanced APM determinations and inform APM Entities or eligible clinicians of those determinations prior to the December 1 QP Determination Submission Deadline. If we determine that an other payer arrangement is not an Other Payer Advanced APM, notifying APM Entities or eligible clinicians of such a determination may help them avoid the burden of submitting payment amount and patient count information for that payment arrangement. We intend to make these early notifications to the extent possible. We propose that APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all of the other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

We seek comment on these proposals.

We note that we will seek OMB approval for the proposed Eligible Clinician Initiated Submission Form separately from this rulemaking process. In accordance with the Paperwork Reduction Act (PRA), we will publish the required 60-day public notice and 30-day public notice. In addition, the entire information collection request and all associated forms will be made available for public review prior to OMB submission.

(2) Medicaid APMs and Medicaid Medical Home Models

In this section, we discuss how payers, APM Entities, and eligible clinicians may request that we determine whether payment arrangements authorized under Title XIX of the Act are Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria. There are some differences between the determination process for other payer arrangements where Medicaid is the payer and the process for other payer arrangements with other types of payers. These differences stem in part from the requirements specified in sections 1833(z)(2)(B)(ii)(bb) and 1833(z)(2)(C)(ii)(bb) of the Act for the All-Payer Combination Option for QP determinations. We interpret those statutory provisions to direct us, when making QP determinations under the All-Payer Combination Option, to exclude from the calculation of ''all other payments'' any payments made (or patients under the patient count method) under Title XIX in a state in which there is no available Medicaid APM (which by definition at § 414.1305 meets the Other Payer Advanced APM criteria) or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria. We believe that our interpretation of the statute to exclude, when appropriate as discussed in section II.D.6.(d)(3)(c) of this proposed rule, Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria, is appropriate to carry out the terms of the statute while avoiding circumstances that could unfairly impact the ability of eligible clinicians to plan ahead and position themselves to attain QP status. Our interpretation leads us to exclude Title XIX payments or patients from the denominator of QP calculations when eligible clinicians had no opportunity to participate in a Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria.

To implement this requirement, we need to determine which states have no available Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria during a given All-Payer QP Performance Period as described in section II.D.6.c.(2)(b) of the proposed rule. We believe that it is important for us to make this determination prior to the All-Payer QP Performance Period, and to announce the Medicaid APMs and Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria and the locations where

they are available, so that eligible clinicians can assess whether their Title XIX payments and patients would be excluded under the All-Payer Combination Option for that particular performance year. If, for a given state, we receive no requests to make determinations for other payer arrangements that could be Medicaid APMs or Medicaid Medical Home Models that are Other Payer Advanced APMs for the year through either the Payer Initiated Process or the Eligible Clinician Initiated Process, we would assume that there are no Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria in that state for the relevant All-Payer QP Performance Period. Accordingly, we would exclude Title XIX payments and patients from the All-Payer Combination Option calculations for eligible clinicians in that state.

(a) Payer Initiated Process

We propose that any states and territories (which we refer to as states) that have in place a state plan under Title XIX may request that we determine prior to the All-Payer QP Performance Period whether other payer arrangements authorized under Title XIX are Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria, in other words, are Other Payer Advanced APMs, under the Payer Initiated Process. States include the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

We propose to allow states to request determinations for both Medicaid fee-for-service and Medicaid managed care plan payment arrangements. States often use managed care plan contracts to implement payment arrangements, and a substantial portion of the Medicaid beneficiary population receives their health care services through Medicaid managed care plans. We expect that states would work closely with their managed care plans to identify and collect relevant information. However, we propose to accept requests regarding payment arrangements authorized under Title XIX under the Payer Initiated Process only from the state, not from a Medicaid managed care plan, as states are responsible ultimately for the administration of their Medicaid programs. Details specific to the Payer Initiated Process for payment arrangements authorized under Title XIX are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Payer Initiated Process for each payer type prior to the first Submission Period, which would occur during 2018. We intend to develop a submission form (which we refer to as the Payer Initiated Submission Form) that would be used by payers to request Other Payer Advanced APM determinations, and we intend to send this Payer Initiated Submission Form to states prior to the first Submission Period. We propose that payers would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to payment arrangements authorized under Title XIX, and we intend for it to include a way for payers to attach supporting documentation. We propose that payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement, and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

We intend to work with states as they prepare and submit Payer Initiated Submission Forms for our review. In completing the Payer Initiated Submission Form, states could refer to information we already possess on their payment arrangements to support their request for a determination. This information could include, for example, submissions that states typically make to us to obtain authorization to modify their Medicaid payment arrangements, such as a State Plan Amendment or an 1115 demonstration's waiver application, Special Terms and Conditions document, implementation protocol document, or other document describing the 1115 demonstration arrangements approved by CMS.

Submission Period: We propose that the Submission Period for the Payer Initiated Process for use by states to request Other Payer Advanced APM determinations for other payer arrangements authorized under Title XIX will open on January 1 of the calendar year prior to the relevant All-Payer QP Performance Period for which we would make the determination for a Medicaid APM or a Medicaid Medical Home Model that is an Other Payer Advanced APM. We propose that the Submission Deadline for these submissions is April 1 of the year prior to the All-Payer QP Performance Period for which we would make the determination. As we discuss in section II.D.6.c.(2) of this proposed rule, we need to determine Medicaid APMs and Medicaid Medical Home Models that are Other Payer Advanced APMs prior to the start of the All-Payer QP Performance Period in order to apply the Title XIX exclusions where appropriate. We propose these dates for this reason, as well as to provide time for APM Entities and eligible clinicians to review the Medicaid APMs and Medicaid Medical Home Models that are Other Payer Advanced APMs on the Other Payer Advanced APM list.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that, if we determine that the state has submitted incomplete or inadequate information, we would inform the state and allow the state to submit additional information no later than 10 business days from the date we inform the state. For each other payer arrangement for which the state does not submit sufficient information, we would not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify states of our determinations for each request as soon as practicable after the relevant Submission Deadline. We propose that states may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs

that we determine based on other requests through the Eligible Clinician Initiated Process.

We intend to implement ongoing assistance through existing conversations or negotiations as states design and develop new payment arrangements that may be identified as Other Payer Advanced APMs. As states begin discussions with us regarding the development of other payer arrangements through the different legal authorities available under Title XIX or Title XI of the Act, we would help states consider and address the Other Payer Advanced APM criteria.

(b) Eligible Clinician Initiated Process

We believe that, to appropriately implement the Title XIX exclusions, it is not feasible to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the All-Payer QP Performance Period for the year, as we are allowing APM Entities and eligible clinicians to do for other payers. To do so would mean that a single clinician requesting a determination for a previously unknown Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county) as described in section II.D.6.d.(3) of this proposed rule. Thus, we would be unable to provide timely notice of the presence of a Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria to all other eligible clinicians in the state whose QP determinations under the All-Payer Combination Option could be affected. To avoid this scenario, we propose to require that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the All-Payer QP Performance Period. This would allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients would be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. Details specific to the Eligible Clinician Initiated Process for payment arrangements authorized under Title XIX are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Eligible Clinician Initiated Process for payment arrangements authorized under Title XIX prior to the first Submission Period, which would occur during 2018. We intend to develop a submission form (which we refer to as the Eligible Clinician Initiated Submission Form) that would be used by APM Entities or eligible clinicians to request Other Payer Advanced APM determinations, and we intend to make this Eligible Clinician Initiated Submission Form available to APM Entities and eligible clinicians prior to the first Submission Period. We propose that APM Entities and eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Eligible Clinician Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to payment arrangements made under Title XIX, and we intend for it to include a way for APM Entities or eligible clinicians to attach supporting documentation. We propose that APM Entities or eligible clinicians may submit requests for review of multiple other payer arrangements through the Eligible Clinician Initiated Process, though we would make separate determinations as to each other payer arrangement and an APM Entity or eligible clinician would be required to use a separate Eligible Clinician Initiated Submission Form for each other payer arrangement. APM Entities or eligible clinicians may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that APM Entities or eligible clinicians may submit Eligible Clinician Initiated Forms for payment arrangements authorized under Title XIX beginning on September 1 of the calendar year prior to the All-Payer QP Performance Period. We also propose that the Submission Deadline is November 1 of the calendar year prior to the All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of an Eligible Clinician Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the APM Entity or eligible clinician and allow the APM Entity or eligible clinician to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify APM Entities and eligible clinicians of our determinations for each other payer arrangement for which a determination was requested as soon as practicable after the relevant Submission Deadline. We propose that APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all of the other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

(c) Summary

The proposed timeline for both the Payer Initiated and Eligible Clinician Initiated Other Payer Advanced APM Determination Processes for payment arrangements authorized under Title XIX are summarized in Table 50.

TABLE 50—OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR PAYMENT ARRANGEMENTS AUTHORIZED UNDER TITLE XIX FOR ALL-PAYER QP PERFORMANCE PERIOD 2019

	Payer Initiated Process	Date	Eligible Clinician (EC) initiated process *	Date
Medicaid	Guidance sent to states, then Submission Period Opens.	Jan. 2018	Guidance made available to ECs—Submission Period Opens.	Sept. 2018.
	Submission Period Closes	April 2018	Submission Period Closes	Nov. 2018.
	CMS contacts states and Posts Other Payer Advanced APM List.	Sept. 2018	CMS contacts ECs and states and Posts Other Payer Advanced APM List.	Dec. 2018.

* Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

(3) CMS Multi-Payer Models

For purposes of carrying out the Quality Payment Program, we propose to define the term CMS-Multi Payer Model at § 414.1305 of our regulations as an Advanced APM that CMS determines, per the terms of the Advanced APM, has at least one other payer arrangement that is designed to align with the terms of that Advanced APM. Examples of CMS Multi-Payer Models include the Comprehensive Primary Care Plus (CPC+) Model, the Oncology Care Model (OCM) (2-sided risk arrangement), and the Vermont All-Payer ACO Model.

Other payer arrangements that are in a CMS Multi-Payer Model, by definition, are not APMs and thus cannot be Advanced APMs under the Medicare Option. We recognize, though, that these other payer arrangements could be Other Payer Advanced APMs. We therefore propose that beginning in the first All-Payer QP Performance Period, payers with other payer arrangements in a CMS Multi-Payer Model may request that we determine whether those aligned other payer arrangements are Other Payer Advanced APMs.

Because there may be differences among the other payer arrangements that are aligned with an Advanced APM in a CMS Multi-Payer Model, we propose to make separate determinations about each of those other payer arrangements on an individual basis. In other words, an other payer arrangement aligned with an Advanced APM in a CMS Multi-Payer Model is not automatically an Other Payer Advanced APM by virtue of its alignment.

We acknowledge that there can be payment arrangements authorized under Title XIX or Medicare Health Plan payment arrangements that are aligned with a CMS Multi-Payer Model. We propose that payers, APM Entities, or eligible clinicians who want to request that we determine whether those arrangements are Other Payer Advanced APMs would use the processes specified for payment arrangements authorized under Title XIX and Medicare Health Plan payment arrangements discussed in sections II.D.6.c.(2) and II.D.6.c.(4) of this proposed rule.

(a) Payer Initiated Process

Details specific to the Payer Initiated Process for payment arrangements in CMS Multi-Payer Models are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Payer Initiated Process for other payer arrangements in CMS Multi-Payer Models prior to the first Submission Period, which would occur during 2018. We intend to develop a submission form (which we refer to as the Payer Initiated Submission Form) that would be used by payers to request Other Payer Advanced APM determinations, and we intend to make this Payer Initiated Submission Form available to payers prior to the first Submission Period. We propose that payers would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to other payer arrangements in CMS Multi-Payer Models, and we intend for it to include a way for payers to attach supporting documentation. We propose that payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that the submission period would open on January 1 of the calendar year prior to the relevant All-Payer QP Performance Period. We also propose that the submission period would close on June 30 of the calendar year prior to the relevant All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the payer has submitted incomplete or inadequate information, we would inform the payer and allow the payer to submit additional information no later than 10 business days from the date we inform the payer. For each other payer arrangement for which the payer does not submit sufficient information, we would not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify payers of our determinations for each request as soon as practicable after the relevant Submission Deadline. We propose that payers may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other

requests through the Eligible Clinician Initiated Process.

(b) Eligible Clinician Initiated Process

Details specific to the Eligible Clinician Initiated Process for payment arrangements in CMS Multi-Payer Models are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Eligible Clinician Initiated Process for payment arrangements in CMS Multi-Payer Models prior to the first Submission Period, which would occur during 2019. We intend to develop a submission form (which we refer to as the Eligible Clinician Initiated Submission Form) that would be used by APM Entities or eligible clinicians to request Other Payer Advanced APM determinations, and we intend to make this Eligible Clinician Initiated Submission Form available to APM Entities and eligible clinicians prior to the first Submission Period. We propose that APM Entities and eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Eligible Clinician Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to other payer arrangements in CMS Multi-Payer Models, and we intend for it to include a way for APM Entities or eligible clinicians to attach supporting documentation. We propose that APM Entities or eligible clinicians may submit requests for review of multiple other payer arrangements through the Eligible Clinician Initiated Process, though we would make separate determinations as to each other payer arrangement. An APM Entity or eligible clinician would be required to use a separate Eligible Clinician Initiated Submission Form for each other payer arrangement. APM Entities or eligible clinicians may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We discuss our proposal to establish the All-Payer QP Performance Period in section II.D.6.(d)(2)(a) of this proposed rule. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of an Eligible Clinician Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the APM Entity or eligible clinician and allow the APM Entity or eligible clinician to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify APM Entities and eligible clinicians of our determinations for each other payer arrangement for which a determination was requested as soon as practicable after the relevant Submission Deadline. We note that APM Entities and eligible clinicians who submit complete Eligible Clinician Initiated Submission Forms by September 1 of the calendar year of the relevant All-Payer QP Performance Period may allow for us to make Other Payer Advanced APM determinations and inform APM Entities or eligible clinicians of those determinations prior to the December 1 QP Determination Submission Deadline. If we determine that an other payer arrangement is not an Other Payer Advanced APM, notifying APM Entities or eligible clinicians of such a determination may help them avoid the burden of submitting payment amount and patient count information for that payment arrangement. We intend to make these early notifications to the extent possible. We propose that APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all of the other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

(c) State All-Payer Models

Some CMS Multi-Payer Models involve an agreement with a state to test an APM and one or more associated other payer arrangements in that state where the state prescribes uniform payment arrangements across state-based payers. As such, we believe it may be appropriate and efficient for states, rather than any other payer, to submit information to us on these payment arrangements for purposes of an Other Payer Advanced APM determination.

We propose that, in CMS Multi-Payer Models where a state prescribes uniform payment arrangements across all payers statewide, the state would submit on behalf of payers in the Payer Initiated Process for Other Payer Advanced APMs; we would seek information for the determination from the state, rather than individual payers. The same Payer Initiated Process and timeline described above for CMS Multi-Payer Models would apply. We seek comment on this proposal. Additionally, we seek comment regarding the effectiveness of taking a similar approach in cases where the state does not require uniform payment arrangements across payers.

(d) Summary

The proposed timelines for both the Payer Initiated and Eligible Clinician Initiated Other Payer Advanced APM Determination Processes for payment arrangements in CMS Multi-Payer Models are summarized in Table 51.

TABLE 51—OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR CMS MULTI-PAYER MODELS FOR ALL-PAYER QP PERFORMANCE PERIOD 2019

	Payer Initiated Process	Date	Eligible Clinician (EC) initiated process *	Date
CMS Multi-Payer Models.	Guidance made available to payers—Submission Period Opens.	Jan. 2018	Guidance made available to ECs—Submission Period Opens.	Aug. 2019.
	Submission Period Closes	June 2018	Submission Period Closes	Dec. 2019.
	CMS contacts payers and Posts Other Payer Advanced APM Lists.	Sept. 2018	CMS contacts ECs and Posts Other Payer Advanced APM List.	Dec. 2019.

* Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

(4) Medicare Health Plans

The Medicare Option for QP determinations under sections 1833(z)(2)(A), (2)(B)(i), and (2)(C)(i) of the Act, is based only on the percentage of Part B payments for covered professional services, or patients, that is attributable to payments through an Advanced APM. As such, payment amounts or patient counts under Medicare Health Plans, including Medicare Advantage, Medicare-Medicaid Plans, 1876 and 1833 Cost Plans, and Programs of All Inclusive Care for the Elderly (PACE) plans, cannot be included in the QP determination calculations under the Medicare Option. (See 81 FR 77473 through 77474). Instead, eligible clinicians who participate in Other Payer Advanced APMs, including those with Medicare Advantage as a payer, could begin receiving credit for that participation through the All-Payer Combination Option in 2021 based on the performance in the 2019 All-Payer QP Performance Period.

In light of these statutory limitations, we have received feedback in support of creating a way for those participating or who could participate in Advanced APMs that include Medicare Advantage to receive credit for that participation in QP determinations under the Medicare Option. We are considering opportunities to address this issue. We seek comment on such opportunities, including potential models and uses of our waiver and demonstration authorities.

Under the All-Payer Combination Option, eligible clinicians can become QPs based in part on payment amounts or patient counts associated with payer arrangements through Medicare Health Plans, provided that such arrangements meet the criteria to be Other Payer Advanced APMs. We note that the financial relationship between the Medicare Health Plan and CMS is not relevant to the Other Payer Advanced APM determination. Rather, because QP determinations are made for eligible clinicians, only the payment arrangement between a Medicare Health Plan and an eligible clinician is relevant when determining whether a payment arrangement is an Other Payer Advanced APM.

(a) Payer Initiated Process

We propose that Medicare Health Plans may request that we determine whether their payment arrangements are Other Payer Advanced APMs prior to the All-Payer QP Performance Period, by submitting information contemporaneously with the annual bidding process for Medicare Advantage contracts (that is., submitted by the first Monday in June of the year prior to the payment and coverage year). Because this is a process in which many Medicare Health Plans currently participate, we believe it will be the least burdensome approach for Medicare Health Plans.

Details specific to the Payer Initiated Process for Medicare Health Plan payment arrangements are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Payer Initiated Process for Medicare Health Plan payment arrangements prior to the first Submission Period, which would occur during 2018. We intend to make guidance available on or around the time of release of the Part C and D Advance Notice and Draft Call Letter the year prior to the relevant All-Payer QP Performance Period. We intend to develop a submission form (which we refer to as the Payer Initiated Submission Form) that would be used by payers to request Other Payer Advanced APM determinations, and we intend to make this Payer Initiated Submission Form available to payers prior to the first Submission Period. This form would be built into the Health Plan Management System (HPMS), which payers currently use for the annual bidding process. We propose that payers would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to Medicare Health Plan payment arrangements, and we intend for it to include a way for payers to attach supporting documentation. We propose that payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that the Submission Period would begin and end at the same time as the annual bid timeframe. We propose the Submission Period would begin when the bid packages are sent out to plans in April of the year prior to the relevant All-Payer QP Performance Period. We also propose that the Submission Deadline would be the annual bid deadline, which would be the first Monday in June in the year prior to the relevant All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the payer has submitted incomplete or inadequate information, we would inform the payer and allow the payer to submit additional information no later than 10 business days from the date we inform the payer. For each other payer arrangement for which the payer does not submit sufficient information, we would not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These

determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify payers of our determinations for each request as soon as practicable after the relevant Submission Deadline. We propose that payers may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

(b) Eligible Clinician Initiated Process

Details specific to the Payer Initiated Process for Medicare Health Plan payment arrangements are explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Eligible Clinician Initiated Process for Medicare Health Plan payment arrangements prior to the first Submission Period, which would occur during 2019. We intend to develop a submission form (which we refer to as the Eligible Clinician Initiated Submission Form) that would be used by APM Entities or eligible clinicians to request Other Payer Advanced APM determinations, and we intend to make this Eligible Clinician Initiated Submission Form available to APM Entities and eligible clinicians prior to the first Submission Period. We propose that APM Entities and eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Eligible Clinician Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to Medicare Health Plan payment arrangements, and we intend for it to include a way for APM Entities or eligible clinicians to attach supporting documentation. We propose that APM Entities or eligible clinicians may submit requests for review of multiple other payer arrangements through the Eligible Clinician Initiated Process, though we would make separate determinations as to each other payer arrangement and an APM Entity or eligible clinician would be required to use a separate Eligible Clinician Initiated Submission Form for each other payer arrangement. APM Entities or eligible clinicians may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We discuss our proposal to establish the All-Payer QP Performance Period in section II.D.6.(d)(2)(a) of this proposed rule. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of an Eligible Clinician Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the APM Entity or eligible clinician and allow the APM Entity or eligible clinician to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify APM Entities and eligible clinicians of our determinations for each other payer arrangement for which a determination was requested as soon as practicable after the relevant Submission Deadline. We note that APM Entities and eligible clinicians who submit complete Eligible Clinician Initiated Submission Forms by September 1 of the calendar year of the relevant All-Payer QP Performance Period may allow for us to make Other Payer Advanced APM determinations and inform APM Entities or eligible clinicians of those determinations prior to the December 1 QP Determination Submission Deadline. If we determine that an other payer arrangement is not an Other Payer Advanced APM, notifying APM Entities or eligible clinicians of such a determination may help them avoid the burden of submitting payment amount and patient count information for that payment arrangement. We intend to make these early notifications to the extent possible. We propose that APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all of the other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

(c) Summary

The proposed timeline for both the Payer Initiated and Eligible Clinician Initiated Other Payer Advanced APM Determination Processes for Medicare Health Plan payment arrangements are summarized in Table 52.

TABLE 52—OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR MEDICARE HEALTH PLAN PAYMENT ARRANGEMENTS FOR ALL-PAYER QP PERFORMANCE PERIOD 2019

	Payer Initiated Process	Date	Eligible Clinician (EC) initiated process *	Date
Medicare Health Plans.	Guidance sent to Medicare Health Plans—Submission Period Opens.	April 2018	Guidance made available to ECs—Submission Period Opens.	Aug. 2019.
	Submission Period Closes	June 2018	Submission Period Closes	Dec. 2019.
	CMS contacts Medicare Health Plans and Posts Other Payer Advanced APM List.	Sept. 2018	CMS contacts ECs and Posts Other Payer Advanced APM List.	Dec. 2019.

* Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

(5) Remaining Other Payers

(a) Payer Initiated Process

We propose to allow the remaining other payers not specifically addressed in proposals above, including commercial and other private payers that are not states, Medicare Health Plans or payers with arrangements that are aligned with a CMS Multi-Payer Model, to request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 All-Payer QP Performance Period and each year thereafter. We seek comment on this proposal, and we also seek comment on potential challenges to these other payers submitting information to us for Other Payer Advanced APM determinations. We intend to discuss this process in more detail in future rulemaking.

(b) Eligible Clinician Initiated Process

We propose that APM Entities and eligible clinicians may request that we determine whether an other payer arrangement with one of these other payers is an Other Payer Advanced APM beginning 2019 All-Payer QP Performance Period as explained below.

Guidance and Submission Form: We intend to make guidance available regarding the Eligible Clinician Initiated Process for remaining other payer arrangements prior to the first Submission Period, which would occur during 2019. We intend to develop a submission form (which we refer to as the Payer Initiated Submission Form) that would be used by APM Entities or eligible clinicians to request Other Payer Advanced APM determinations, and we intend to make this Eligible Clinician Initiated Submission Form available to APM Entities and eligible clinicians prior to the first Submission Period. We propose that APM Entities and eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Eligible Clinician Initiated Submission Form to include questions that are applicable to all other payer arrangements and some that are specific to remaining other payer arrangements, and we intend for it to include a way for APM Entities or eligible clinicians to attach supporting documentation. We propose that APM Entities or eligible clinicians may submit requests for review of multiple other payer arrangements through the Eligible Clinician Initiated Process, though we would make separate determinations as to each other payer arrangement and an APM Entity or eligible clinician would be required to use a separate Eligible Clinician Initiated Submission Form for each other payer arrangement. APM Entities or eligible clinicians may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

Submission Period: We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We discuss our proposal to establish the All-Payer QP Performance Period in section II.D.6.(d)(2)(a) of this proposed rule. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

CMS Determination: Upon the timely receipt of an Eligible Clinician Initiated Submission Form, we would use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We propose that if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the APM Entity or eligible clinician and allow the APM Entity or eligible clinician to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form. As a result, the other payer arrangement would not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

CMS Notification: We propose to notify APM Entities and eligible clinicians of our determinations for each other payer arrangement for which a determination was requested as soon as practicable after the relevant Submission Deadline. We note that APM Entities and eligible clinicians who submit complete Eligible Clinician Initiated Submission Forms by September 1 of the calendar year of the relevant All-Payer QP Performance Period may allow for us to make Other Payer Advanced APM determinations and inform APM Entities or eligible clinicians of those determinations prior to the December 1 QP Determination Submission Deadline. If we determine that an other payer arrangement is not an Other Payer Advanced APM, notifying APM Entities or eligible clinicians of such a determination may help them avoid the burden of submitting payment amount and patient count information for that payment arrangement. We intend to make these early notifications to the extent possible. We propose that APM Entities or eligible clinicians may submit information regarding an other payer arrangement for a subsequent All-Payer QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS Web site a list (which we refer to as the Other Payer Advanced APM List) of all of the other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant All-Payer QP Performance Period, we intend to post the Other Payer Advanced APMs that we determine

through the Payer Initiated Process and Other Payer Advanced APMs under Title XIX that we determine through the Eligible Clinician Initiated Process. After the All-Payer QP Performance Period, we would update this list to include Other Payer Advanced APMs that we determine based on other requests through the Eligible Clinician Initiated Process.

We seek comments on these proposals.

(c) Summary

The proposed timeline for both the Payer Initiated and Eligible Clinician Initiated Other Payer Advanced APM Determination Processes for payment arrangements for remaining other payers are summarized in Table 53.

TABLE 53—OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR REMAINING OTHER PAYER PAYMENT ARRANGEMENTS FOR ALL-PAYER QP PERFORMANCE PERIOD 2019

	Eligible Clinician (EC) initiated process *	Date
Remaining Other Payers	Guidance made available to ECs—Submission Period Opens	Aug. 2019.
	Submission Period Closes	Dec. 2019.
	CMS contacts ECs and Posts Other Payer Advanced APM List	Dec. 2019.

* Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

(6) Timeline for the Proposed Other Payer Advanced APM Determination Processes

The proposed timeline for both the proposed Payer Initiated and Eligible Clinician Initiated Other Payer Advanced APM Determination Processes for all payer types is presented in Table 54.

TABLE 54—TIMELINE FOR OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR THE 2019 QP PERFORMANCE PERIOD BY PAYER TYPE *

Year	Date	Payment arrangements authorized under Title XIX	Payment arrangements in CMS Multi-Payer Models	Medicare Health Plan payment arrangements	Remaining other payer payment arrangements
2018 ...	January	Guidance sent to states—Submission Period Opens.	Guidance made available to payers—Submission Period Opens.	.....	
	April	Submission Period Closes for states.	.....	Guidance sent to Medicare Health Plans—Submission Period Opens.	
	June	Guidance made available to ECs—Submission Period Opens for ECs.	Submission Period Closes for Payers.	Submission Period Closes for Medicare Health Plans.	
	July–August	CMS makes Other Payer Advanced APM Determinations for states.	CMS makes Other Payer Advanced APM Determinations for payers.	CMS makes Other Payer Advanced APM Determinations for Medicare Health Plans.	
	September	CMS posts Other Payer Advanced APM List.	CMS posts Other Payer Advanced APM List.	CMS posts Other Payer Advanced APM List.	
	November	Submission Period Closes for ECs.	.....	.....	
	December	CMS posts Other Payer Advanced APM List.	.....	.....	
2019 ...	August	Submission Period Opens for ECs.	Submission Period Opens for ECs.	Submission Period Opens for ECs.	Submission Period Opens for ECs.
	September	.....	Latest time where ECs can request Other Payer Advanced APM determinations to get notification prior to close of data submission period. Submission Period for QP determination data opens.	Latest time where ECs can request Other Payer Advanced APM determinations to get notification prior to close of data submission period. Submission Period for QP determination data opens.	Latest time where ECs can request Other Payer Advanced APM determinations to get notification prior to close of data submission period. Submission Period for QP determination data opens.

TABLE 54—TIMELINE FOR OTHER PAYER ADVANCED APM DETERMINATION PROCESS FOR THE 2019 QP PERFORMANCE PERIOD BY PAYER TYPE *—Continued

Year	Date	Payment arrangements authorized under Title XIX	Payment arrangements in CMS Multi-Payer Models	Medicare Health Plan payment arrangements	Remaining other payer payment arrangements
	December	.....	Submission Period Closes for EC requests for Other Payer Advanced APM determinations and QP determination data. CMS makes Other Payer Advanced APM Determinations for ECs. CMS posts Other Payer Advanced APM List.	Submission Period Closes for EC requests for Other Payer Advanced APM determinations and QP determination data. CMS makes Other Payer Advanced APM Determinations for ECs. CMS posts Other Payer Advanced APM List.	Submission Period Closes for EC requests for Other Payer Advanced APM determinations and QP determination data. CMS makes Other Payer Advanced APM Determinations for ECs. CMS posts Other Payer Advanced APM List.

*The process repeats beginning in 2019 for the 2020 QP Performance Period.

(7) Submission of Information for Other Payer Advanced APM Determinations

In the CY 2017 Quality Payment Program final rule, we finalized that to be assessed under the All-Payer Combination Option, APM Entities or eligible clinicians must submit, in a manner and by a date that we specify, payment arrangement information necessary to assess whether the other payer arrangement meets the Other Payer Advanced APM criteria (81 FR 77480).

(a) Required Information

As we discuss in sections II.D.6.c.(1) through II.D.6.c.(5) of this proposed rule, we propose to allow for certain types of payers as well as APM Entities or eligible clinicians to request that we determine whether certain other payer arrangements are Other Payer Advanced APMs.

(i) Payer Initiated Process

We intend to create a Payer Initiated Submission Form that would allow payers to submit the information necessary for us to determine whether a payment arrangement is an Other Payer Advanced APM. We propose that, for each other payer arrangement a payer requests us to determine whether it is an Other Payer Advanced APM, the payer must use, complete, and submit the Payer Initiated Submission Form by the relevant deadline.

For us to make these determinations, we propose to require that payers submit the following information for each other payer arrangement:

- Arrangement name;
- Brief description of the nature of the arrangement;
- Term of the arrangement (anticipated start and end dates);
- Participant eligibility criteria;
- Locations (nationwide, state, or county) where this other payer arrangement will be available;
- Evidence that the CEHRT criterion set forth in § 414.1420(b) is satisfied;
- Evidence that the quality measure criterion set forth in § 414.1420(c) is satisfied; including an outcome measure;
- Evidence that the financial risk criterion set forth in § 414.1420(d) is satisfied; and
- Other documentation as may be necessary for us to determine that the other payer arrangement is an Other Payer Advanced APM.

We propose that the Payer Initiated Submission Form would allow payers to include descriptive language for each of the required information elements. We are proposing to require the name and description of the arrangement, nature of the arrangement, term of the arrangement, eligibility criteria, and location(s) where the arrangement will be available so that we can verify whether eligible clinicians who may tell us that they participate in such arrangements are eligible to do so. We require evidence that all of the Other Payer Advanced APM criteria are met in order for us to determine whether the arrangement is an Other Payer Advanced APM. We propose that a submission for an Other Payer Advanced APM determination submitted by the payer is complete only if all of these information elements are submitted to us.

We propose to require that payers submit documentation that supports the information they provided in the Payer Initiated Submission Form and that is sufficient to enable us to determine whether the other payer arrangement is an Other Payer Advanced APM. Examples of such documentation would include contracts and other relevant documents that govern the other payer arrangement that verify each required information element, copies of their full contracts governing the arrangement, or some other documents that detail and govern the payment arrangement.

(ii) Eligible Clinician Initiated Process

We intend to create an Eligible Clinician Initiated Submission Form that would allow for APM Entities or eligible clinicians to submit the information necessary for us to determine whether a payment arrangement is an Other Payer Advanced APM. We propose that, for each other payer arrangement an APM Entity or eligible clinician requests us to determine whether it is an Other Payer Advanced APM, the APM Entity or eligible clinician must use, complete, and submit the Eligible Clinician Initiated Submission Form by the relevant deadline.

For us to make these determinations, we propose to require that the APM Entity or eligible clinician submit the following information for each other payer arrangement:

- Arrangement name;
- Brief description of the nature of the arrangement;
- Term of the arrangement (anticipated start and end dates);
- Locations (nationwide, state, or county) where this other payer arrangement will be available;
- Evidence that the CEHRT criterion set forth in § 414.1420(b) is satisfied;
- Evidence that the quality measure criterion set forth in § 414.1420(c) is satisfied, including an outcome measure;
- Evidence that the financial risk criterion set forth in § 414.1420(d) is satisfied; and
- Other documentation as may be necessary for us to determine whether the other payer arrangement is an Other Payer Advanced APM.

We propose that the Eligible Clinician Initiated Submission Form would allow APM Entities and eligible clinicians to include descriptive language for each of the required information elements. We

are proposing to require the name and description of the arrangement, nature of the arrangement, term of the arrangement, eligibility criteria, and, in the case of Title XIX arrangements only, location(s) where the arrangement will be available. We require evidence that all of the Other Payer Advanced APM criteria are met in order for us to determine that the arrangement is an Other Payer Advanced APM. We propose that a submission for an Other Payer Advanced APM determination submitted by the APM Entity or eligible clinician is complete only if all of these information elements are submitted to us.

We propose to require that APM Entities or eligible clinicians submit documentation that supports the information they provided in the Eligible Clinician Initiated Submission Form and that is sufficient to enable us to determine whether the other payer arrangement is an Other Payer Advanced APM. Examples of such documentation would include contracts and other relevant documents that govern the other payer arrangement that verify each required information element, copies of their full contracts governing the arrangement, or some other documents that detail and govern the payment arrangement. In addition to requesting that we determine whether one or more other payer arrangements are Other Payer Advanced APMs for the year, APM Entities or eligible clinicians may also inform us that they are participating in an other payer arrangement that we determine to be an Other Payer Advanced APM for the year. To do so, we propose that an APM Entity or eligible clinician would indicate, upon submission of Other Payer Advanced APM participation data for purposes of QP determination, which Other Payer Advanced APMs they participated in during the All-Payer QP Performance Period, and include copies of participation agreements or similar contracts (or relevant portions of them) to document their participation in those payment arrangements.

We acknowledge that there is some burden associated with requesting Other Payer Advanced APM determinations. We seek comment on ways to reduce burden on states, payers, APM Entities, and eligible clinicians while still allowing us to receive the information necessary to make such determinations.

(b) Certification and Program Integrity

(i) Payer Initiated Process

We believe that it is important that the information submitted by payers through the Payer Initiated Process is true, accurate, and complete. To that end, we propose to add a new requirement at § 414.1445(d) stating that a payer that submits information pursuant to § 414.1445(c) must certify to the best of its knowledge that the information it submitted to us through the Payer Initiated Process is true, accurate, and complete. Additionally, we propose that this certification must accompany the Payer Initiated Submission Form and any supporting documentation that payers submit to us through this process.

We propose to revise and clarify the monitoring and program integrity provisions at § 414.1460. First, we propose to modify § 414.1460(c) to specify that information submitted by payers for purposes of the All-Payer Combination Option may be subject to audit by us. We anticipate that the purpose of any such audit would be to verify the accuracy of an Other Payer Advanced APM determination. We seek comment on how this might be done with minimal burden to payers. Second, we propose at § 414.1460(e)(1) to require payers who choose to submit information through the Payer Initiated Process to such books, contracts, records, documents, and other evidence as necessary to audit an Other Payer Advanced APM determination. We propose that such information must be maintained for 10 years after submission. We also propose at § 414.1460(e)(3) that such information and supporting documentation must be provided to us upon request. We request comments on this proposal, including comment on the length of time payers typically maintain such information. We also seek comment on how this might be done with minimal burden to payers.

(ii) Eligible Clinician Initiated Process

In the CY 2017 Quality Payment Program final rule, we finalized a requirement at § 414.1445(b)(3) that payers must attest to the accuracy of information submitted by eligible clinicians (81 FR 77480). After publication of the final rule, we received comments from stakeholders opposing this requirement. Commenters noted that payers may not have any existing relationship with us, that payers do not have any direct stake in the QP status of eligible clinicians, and that there may be operational and legal barriers to payers attesting to this information. In consideration of these comments, we propose to eliminate the requirement at § 414.1445(b)(3) that payers attest that the information submitted by eligible clinicians is accurate. Instead, as discussed in section II.D.6.c.(7)(b)(i) of this rule, we are proposing that payers must certify only the information they submit directly to us.

In the CY 2017 Quality Payment Program final rule, we finalized a requirement at § 414.1460(c) that eligible clinicians and APM Entities must attest to the accuracy and completeness of data submitted to meet the requirements under the All-Payer Combination Option. We believe this requirement would be more appropriately placed in the regulatory provisions that discuss the submission of information related to requests for Other Payer Advanced APM determinations. Accordingly, we are proposing to remove this requirement at § 414.1460(c) and proposing at § 414.1445(d) that an APM Entity or eligible clinician that submits information pursuant to § 414.1445(c) must certify to the best of its knowledge that the information it submitted to us is true, accurate, and complete. In the case of information submitted by the APM Entity, we propose that the certification be made by a person with the authority to bind the APM Entity. We also propose that this certification accompany the Eligible Clinician Initiated Submission Form and any supporting documentation that eligible clinicians submit to us through this process. We note that under § 414.1460(c), APM Entities or eligible clinicians may be subject to audit of the information and supporting documentation provided under the certification. In section II.D.6.c.(7)(b) of this rule, we discuss our proposal to add a similar certification requirement at § 414.1440(f)(2) for QP determinations. We note that we propose to remove the last sentence of § 414.1460(c) regarding record retention and address the record retention issue only in the maintenance of records provision at § 414.1460(e).

Finally, we are proposing to clarify the nature of the information subject to the record retention requirements at § 414.1460(e). Specifically, we propose that an APM Entity or eligible clinician must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determination, and the accuracy of an APM Incentive Payment.

(iii) Outcome Measure

For both Advanced APMs and Other Payer Advanced APMs, we want to encourage the use of outcome measures for quality performance assessment. We also recognize there is a lack of appropriate outcome measures for use

by certain specialties and take that into consideration when interpreting the requirement that an Other Payer Advanced APM is one under which MIPS-comparable quality measures apply. Therefore, in the CY 2017 Quality Payment Program final rule, we finalized at § 414.1420(c)(3) that to meet the quality measure use criterion to be an Other Payer Advanced APM, the other payer arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list; but if there is no outcome measure available for use in the other payer arrangement, the APM Entity must attest that there is no applicable measure on the MIPS quality measure list. While we are not proposing substantive changes to this policy, we are making technical revisions to our regulations to codify this policy at § 414.1445(c)(3) and we clarify that a payer, APM entity, or eligible clinician must certify that there is no applicable measure on the MIPS quality measure list if the payment arrangement does not use an outcome measure.

(c) Use of Information Submitted

We intend to post, on a CMS Web site, only the following information about other payer arrangements that we determine are Other Payer Advanced APMs: The names of payers with Other Payer Advanced APMs as specified in either the Payer Initiated or Eligible Clinician Initiated Submission Form, the location(s) in which the Other Payer Advanced APMs are available whether at the nationwide, state, or county level, and the names of the specific Other Payer Advanced APMs.

We believe that making this information publicly available is particularly important for Medicaid APMs and Medicaid Medical Home Models so that eligible clinicians can assess whether their Medicaid payments and patients would be excluded in calculations under the All-Payer Combination Option. More generally, we believe that making this information publicly available would help eligible clinicians to identify which of their other payer arrangements are Other Payer Advanced APMs so they can include information on those Other Payer Advanced APMs in their requests for QP determinations; and to learn about, and potentially join, Other Payer Advanced APMs that may be available to them. We seek comment on whether posting this information would be helpful to APM Entities or eligible clinicians.

In the CY 2017 Quality Payment Program final rule, we finalized that, to the extent permitted by federal law, we would maintain confidentiality of certain information that APM Entities or eligible clinicians submit for purposes of Other Payer Advanced APM determinations to avoid dissemination of potentially sensitive contractual information or trade secrets (81 FR 77478 through 77480).

We propose that, with the exception of the specific information we propose to make publicly available as stated above, the information a payer submits to us through the Payer Initiated Process and the information an APM Entity or eligible clinician submits to us through the Eligible Clinician Initiated Process would be kept confidential to the extent permitted by federal law, in order to avoid dissemination of potentially sensitive contractual information or trade secrets.

We seek comment on this proposal.

(d) Use of Certified EHR Technology (CEHRT)

In the CY 2017 Quality Payment Program final rule, we finalized that to be an Other Payer Advanced APM, the other payer arrangement must require at least 50 percent of participating eligible clinicians in each APM Entity to use Certified EHR Technology (CEHRT) to document and communicate clinical care (81 FR 77465).

We believe that some other payer arrangements, particularly those for which eligible clinicians may request determinations as Other Payer Advanced APMs, may only require CEHRT use at the individual eligible clinician level in the contract the eligible clinician has with the payer. We also believe that it may be challenging for eligible clinicians to submit information sufficient for us to determine that at least 50 percent of eligible clinicians under the other payer arrangement are required to use CEHRT to document and communicate clinical care.

To address this issue, we propose that we would presume that an other payer arrangement would satisfy the 50 percent CEHRT use criterion if we receive information and documentation from the eligible clinician through the Eligible Clinician Initiated Process showing that the other payer arrangement requires the requesting eligible clinician(s) to use CEHRT to document and communicate clinician information. We seek comment on this proposal. We also seek comment on what kind of requirements for CEHRT currently exist in other payer arrangements, particularly if they are written to apply at the eligible clinician level.

(8) Summary of Proposals

In summary, we are proposing the following:

Payer Initiated Process

- We propose to allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements in CMS Multi-Payer Models to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 All-Payer QP Performance Period and each year thereafter. We propose to allow remaining other payers, including commercial and other private payers, to request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 All-Payer QP Performance Period, and annually each year thereafter. We propose to generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process), and we propose that the Payer Initiated Process would generally involve the same steps for each payer type for each All-Payer QP Performance Period. If a payer uses the same other payer arrangement in other commercial lines of business, we propose to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well.
- We propose that these Other Payer Advanced APM determinations would be in effect for only one year at a time.
- We propose that the Payer Initiated Process would be voluntary for all payers.
- We propose that payers would be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We propose that the Submission Period opening date and Submission Deadline would vary by payer type to align with existing CMS processes for payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements in CMS Multi-Payer Models to the extent possible and appropriate.
- We propose that if we determine that the payer has submitted incomplete or inadequate information, we would inform the payer and allow the payer to submit additional information no later than 10 business days from the date we inform the payer. For each other payer arrangement for which the payer does not submit sufficient information, we

would not make a determination in response to that request submitted via the Payer Initiated Submission Form.

- *Title XIX (Medicaid):* We propose that any states and territories (''states'') that have in place a state plan under Title XIX may request that we determine prior to the All-Payer QP Performance Period whether other payer arrangements authorized under Title XIX are Other Payer Advanced APMs under the Payer Initiated Process. We propose to allow states to request determinations for both Medicaid fee-for-service and Medicaid managed care plan payment arrangements. We propose that the Submission Period for the Payer Initiated Process for use by states to request Other Payer Advanced APM determinations for other payer arrangements authorized under Title XIX will open on January 1 of the calendar year prior to the relevant All-Payer QP Performance Period for which we would make the determination for a Medicaid APM or a Medicaid Medical Home Model that is an Other Payer Advanced APM. We propose that the Submission Deadline for these submissions is April 1 of the year prior to the All-Payer QP Performance Period for which we would make the determination.
- *CMS Multi-Payer Models:* We propose that payers with other payer arrangements aligned with a CMS Multi-Payer Model may request that we determine whether their aligned other payer arrangements are Other Payer Advanced APMs. We propose that payers with other payer arrangements in a CMS Multi-Payer Model may request that we determine prior to the All-Payer QP Performance Period whether those other payer arrangements are Other Payer Advanced APMs. We propose that payers that want to request that we determine whether those arrangements are Other Payer Advanced APMs would use the processes specified for payment arrangements authorized under Title XIX and Medicare Health Plan payment arrangements. We propose that the submission period would open on January 1 of the calendar year prior to the relevant All-Payer QP Performance Period. We also propose that the submission period would close on June 30 of the calendar year prior to the relevant All-Payer QP Performance Period. We propose that, in CMS Multi-Payer Models where a state prescribes uniform payment arrangements across all payers statewide, the state would submit on behalf of payers in the Payer Initiated Process for Other Payer Advanced APMs; we would seek information for the determination from the state, rather than individual payers. The same Payer Initiated Process and timeline described above for CMS Multi-Payer Models would apply.
- *Medicare Health Plans:* We propose that the Submission Period would begin and end at the same time as the annual bid timeframe. We propose the Submission Period would begin when the bid packages are sent out to plans in April of the year prior to the relevant All-Payer QP Performance Period. We also propose that the Submission Deadline would be the annual bid deadline, which would be the first Monday in June in the year prior to the relevant All-Payer QP Performance Period.
- *Remaining Other Payers:* We propose to allow the remaining other payers not specifically addressed in proposals above, including commercial and other private payers that are not states, Medicare Health Plans, or payers with arrangements that are aligned with a CMS Multi-Payer Model, to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 All-Payer QP Performance Period and each year thereafter.

Eligible Clinician Initiated Process

- We propose that through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process could also be used to request determinations before the beginning of an All-Payer Payer QP Performance Period for other payer arrangements authorized under Title XIX.
- We propose that APM Entities or eligible clinicians would be required to use the Eligible Clinician Initiated Submission Form to request that we make an Other Payer Advanced APM determination.
- We propose that if we determine that the APM Entity or eligible clinician has submitted incomplete or inadequate information, we would inform the payer and allow the payer to submit additional information no later than 10 business days from the date we inform the APM Entity or eligible clinician. For each other payer arrangement for which the APM Entity or eligible clinician does not submit sufficient information, we would not make a determination in response to that request submitted via the Eligible Clinician Initiated Submission Form.
- *Title XIX (Medicaid):* We propose that for the first All-Payer QP Performance Period, APM Entities and eligible clinicians may submit information on payment arrangements authorized under Title XIX to request that we determine whether those arrangements are Medicaid APMs or Medicaid Medical Home Models that meet the Other Payer Advanced APM criteria prior to the All-Payer QP Performance Period. We propose that APM Entities or eligible clinicians may submit Eligible Clinician Initiated Forms for payment arrangements authorized under Title XIX beginning on September 1 of the calendar year prior to the All-Payer QP Performance Period. We also propose that the Submission Deadline is November 1 of the calendar year prior to the All-Payer QP Performance Period.
- *CMS Multi-Payer Models:* We propose that through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements in CMS Multi-Payer Models may request that we determine whether those other payer arrangements are Other Payer Advanced APMs. We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.
- *Medicare Health Plans:* We propose that through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements in Medicare Health Plans would have an opportunity to request that we determine whether those other payer arrangements that are not already determined to be Other Payer Advanced APMs through the Payer Initiated Process are Other Payer Advanced APMs. We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

• *Remaining Other Payers:* We propose that through the Eligible Clinician Initiated Process APM Entities and eligible clinicians participating in other payer arrangements through one of these other payers is an Other Payer Advanced APM. We propose that APM Entities or eligible clinicians may request Other Payer Advanced APM determinations beginning on August 1 of the same year as the relevant All-Payer QP Performance Period. We propose that the Submission Deadline for requesting Other Payer Advanced APM determinations, as well as to request QP determinations under the All-Payer Combination Option, is December 1 of the same year as the relevant All-Payer QP Performance Period.

Submission of Information for Other Payer Advanced APM Determinations

• We propose that, for each other payer arrangement a payer requests us to determine whether it is an Other Payer Advanced APM, all payers must complete and submit the Payer Initiated Submission Form by the relevant Submission Deadline. We propose that the Payer Initiated Submission Form would allow payers to include descriptive language for each of the required information elements. We are proposing to require the name and description of the arrangement, nature of the arrangement, term of the arrangement, eligibility criteria, and location(s) where the arrangement will be available so that we can verify whether eligible clinicians who may tell us that they participate in such arrangements are eligible to do so. We propose to require that payers submit documentation that supports the information they provided in the Payer Initiated Submission Form and that is sufficient to enable us to determine whether the other payer arrangement is an Other Payer Advanced APM.

• We propose that, for each other payer arrangement an APM Entity or eligible clinician requests us to determine whether it is an Other Payer Advanced APM, all payers must complete and submit the Eligible Clinician Initiated Submission Form by the relevant deadline. We propose that the Eligible Clinician Initiated Submission Form would allow APM Entities or eligible clinicians to include descriptive language for each of the required information elements. We are proposing to require the name and description of the arrangement, nature of the arrangement, term of the arrangement, eligibility criteria, and location(s) where the arrangement will be available so that we can verify whether eligible clinicians who may tell us that they participate in such arrangements are eligible to do so. We propose to require that APM Entities or eligible clinicians submit documentation that supports the information they provided in the Eligible Clinician Initiated Submission Form and that is sufficient to enable us to determine whether the other payer arrangement is an Other Payer Advanced APM.

• We propose that, for each other payer arrangement a payer requests us to determine whether it is an Other Payer Advanced APM, the payer must complete and submit the Payer Initiated Submission Form by the relevant deadline.

• We propose that, for each other payer arrangement an APM Entity or eligible clinician requests us to determine whether it is an Other Payer Advanced APM, the APM Entity or eligible clinician must complete and submit the Eligible Clinician Initiated Submission Form by the relevant deadline.

• We propose to add a new requirement at § 414.1445(d) stating that a payer that submits information pursuant to § 414.1445(c) must certify to the best of its knowledge that the information submitted to us through the Payer Initiated Process is true, accurate, and complete. Additionally, we propose that this certification must accompany the Payer Initiated Submission Form and any supporting documentation that payers submit to us through this process.

• We also propose to revise the monitoring and program integrity provisions at § 414.1460 to ensure the integrity of the Payer Initiated Process. Specifically, we are proposing to require payers that choose to submit information through the Payer Initiated Process to maintain such books, contracts, records, documents, and other evidence as necessary to audit an Other Payer Advanced APM determination and that such information and supporting documentation must be maintained for 10 years after submission and must be provided to CMS upon request. We also propose to specify that information submitted by payers for purposes of the All-Payer Combination Option may be subject to audit by CMS.

• We are proposing to remove the requirement at § 414.1445(b)(3) that payers must attest to the accuracy of information submitted by eligible clinicians. We are also proposing to remove the attestation requirement at § 414.1460(c) and add a requirement at § 414.1445(d) that an APM Entity or eligible clinician that submits information pursuant to § 414.1445(c) must certify to the best of its knowledge that the information it submitted to us is true, accurate, and complete. We also propose that this certification must accompany the submission.

• We propose to remove the record retention requirement at § 414.1445(c) and only address the record retention issue at § 414.1445(e) stating that APM Entities and eligible clinicians must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determination, and the accuracy of an APM Incentive Payment.

• We propose that, with the exception of the specific information we propose to make publicly available as stated above, the information a payer submits to us through the Payer Initiated Process and the information an APM Entity or eligible clinician submits to us through the Eligible Clinician Initiated Process would be kept confidential to the extent permitted by federal law, in order to avoid dissemination of potentially sensitive contractual information or trade secrets.

• We propose that we would initially presume that an other payer arrangement would satisfy the 50 percent CEHRT use criterion if we receive information and documentation from the APM Entity or eligible clinician through the Eligible Clinician Initiated Process showing that the other payer arrangement requires the requesting eligible clinician(s) to use CEHRT to document and communicate clinical information.

d. Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

(1) Overview

In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77463). Beginning in 2021, in addition to the Medicare Option, an eligible clinician may alternatively become a QP through the All-Payer Combination Option, and an eligible clinician need only meet the QP threshold under one of the two options to be a QP for the payment year (81 FR 77459). We finalized that we will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77439).

We finalized that we will calculate Threshold Scores under the Medicare Option through both the payment amount and patient count methods,

compare each Threshold Score to the relevant QP and Partial QP thresholds, and use the most advantageous score to make QP determinations (81 FR 77457). We finalized the same approach for the All-Payer Combination Option (81 FR 77475).

Sections 1833(z)(2)(B)(ii)(I) and (C)(ii)(I) of the Act specify that the all payer portion of the Threshold Score calculations under the All-Payer Combination Option is based on the sum of payments for Medicare Part B covered professional services furnished by the eligible clinician and, with certain exceptions, all other payments regardless of payer. We finalized that we would include such payments in the numerator and denominator, and we would exclude the following excepted categories of payments made to the eligible clinician and associated patients from the calculations:

- By the Secretary of Defense;
- By the Secretary of Veterans Affairs; and
- Under Title XIX in a state in which no Medicaid Medical Home Model or APM is available under the state plan.

We finalized this exclusion of payments under Title XIX to mean that Medicaid payments and patients should be excluded from the all-payer calculation under the All-Payer Combination Option, unless:

++ A state has in operation at least one Medicaid APM or Medicaid Medical Home Model that is determined to be an Other Payer Advanced APM; and

++ The relevant APM Entity is eligible to participate in at least one of such Other Payer Advanced APMs during the QP Performance Period, regardless of whether the APM Entity actually participates in such Other Payer Advanced APMs.

(2) Timing of QP Determinations Under the All-Payer Combination Option

In the CY 2017 Quality Payment Program final rule, we finalized that the QP Performance Period for both the Medicare Option and the All-Payer Combination Option would begin on January 1 and end on August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446–77447).

(a) All-Payer QP Performance Period and Medicare QP Performance Period

Upon further consideration, we propose to establish a separate QP Performance Period for the All-Payer Combination Option, which would begin on January 1 and end on June 30 of the calendar year that is 2 years prior to the payment year. We propose to define this term in § 414.1305 as the All-Payer QP Performance Period. The QP Performance Period for the Medicare Option will remain the same as previously finalized, so it would begin on January 1 and end on August 31 of the calendar year that is 2 years to the payment year. We propose to define this term in § 414.1305 as the Medicare QP Performance Period.

We are proposing to establish the All-Payer QP Performance Period because, to make QP determinations under the All-Payer Combination Option, we first need to collect information on eligible clinicians' payments and patients with all other payers. In order to provide eligible clinicians with timely QP determination that would enable them to make their own timely decisions for purposes of MIPS based on their QP status for the year, we need to collect this information by December 1 of the QP performance year. We are concerned that eligible clinicians would not be able to submit the necessary payment and patient information from all of their other payers for the period from January 1 through August 31 before the December 1 Information Submission Deadline. For the Medicare Option, we allow for a 90 day claims run out period before gathering the necessary payment amount and patient count information. We believe the same claims run out timeframe should be adopted for other payers. If we were to maintain the current QP Performance Period through August 31 eligible clinicians would be required to submit their other payer payment and patient information to us on or very near the end of the 90 day claims run out period leaving them with little or no time to prepare the submission. We also believe that an additional 60 days after the claims run out is a reasonable amount of time for the eligible clinician to collect and submit the payment and patient data. We seek comment on this proposal, specifically as to an appropriate claims run out standard for other payers.

If we retained the current QP Performance Period and instead delayed the submission deadline to allow eligible clinicians time comparable to the time provided under the Medicare Option to fully collect and submit this information, QP determinations under the All-Payer Combination Option would likely not be complete before the end of the MIPS reporting period, which would undermine our goal of giving eligible clinicians information about their QP status prior to the end of the MIPS reporting period.

Alternatively, we are considering whether to establish the All-Payer QP Performance Period from January 1 through March 31 of the calendar year that is 2 years prior to the payment year. We believe this option would provide the most ample time possible for eligible clinicians to prepare and submit information to enable us to make a QP determination under the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized a snapshot approach that allows an eligible clinician to attain QP status based on Advanced APM participation from January 1 through March 31 under the Medicare Option. Since QP determinations under the Medicare Option can be based on participation information for January 1 through March 31 of a year, we believe this alternative performance period under the All-Payer Combination Option would not be inconsistent with the policy that we finalized last year, and seek comment on this alternative approach. We seek comments on the establishment of a January 1 through March 31 All-Payer QP Performance Period and whether additional requirements may be needed to ensure the appropriate inplementation of this proposal.

We seek comment on the proposed All-Payer QP Peformance Period from January 1 through June 30 of the year that is 2 years prior to the payment year, and a possible alternative All-Payer QP Performance Period that would be from January 1 through March 31. If we do not finalize the proposed or alternative All-Payer QP Performance Period, we would retain the QP Performance Period that we finalized in the CY 2017 Quality Payment Program final rule, which is from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We are particularly concerned about the potential delay or run out from other payers that may affect the ability of APM entities or eligible clinicians to gather and submit the necessary payment amount and patient count information for the applicable All-Payer QP Performance Period by the December 1 All-Payer QP Determination Submission Deadline. At the same time, we recognize the need to balance this concern with the benefit of collecting Other Payer Advanced APM participation information over a meaningful period of time. We seek comment on the feasibility or difficulty in gathering and submitting this information for each of the potential performance period time frames.

(b) Alignment of Time Periods Assessed Under the Medicare Option and the All-Payer Combination Option

In the CY 2017 Quality Payment Program final rule, we finalized that we will make QP determinations under the

Medicare Option using three snapshot dates during the QP Performance Period on March 31, June 30, and August 31 (81 FR 77446 through 77447).

Consistent with our proposal to make the All-Payer QP Performance Period from January 1 through June 30 of the calendar year that is 2 years prior to the payment year, we propose to make QP determinations based on eligible clinicians' participation in Advanced APMs and Other Payer Advanced APMs between January 1 through March 31 and January 1 through June 30 under the All-Payer Combination Option.

We also propose that an eligible clinician would need to meet the relevant QP or Partial QP Threshold under the All-Payer Combination Option, and we would use data for the same time periods for Medicare payments or patients and that of other payers. For example, we would not assess an eligible clinician under the All-Payer Combination Option using their Advanced APM payment amount and patient count information from January 1 through March 31 and their Other Payer Advanced APM payment amount and patient count information from January 1 through June 30. We are proposing to align the time period assessed for the for the Medicare and other payer portions of the calculations under the All-Payer Combination Option because we believe that would support the principle that QP determinations should be based on an eligible clinician's performance over a single period of time, and that lack of alignment, comingling participation information from multiple time periods for the purposes of making QP determinations, would not appropriately reflect the structure of QP assessment using the All-Payer Combination Option. We seek comment on this proposal.

(c) Notification of QP Determinations Under the All-Payer Combination Option

Our goal, under both the Medicare Option and the All-Payer Combination Option, is to notify eligible clinicians of their QP status at a time that gives any Partial QPs time to decide whether to report to MIPS and gives those eligible clinicians who are not QPs or Partial QPs sufficient notice of the need to report to MIPS. For the All-Payer Combination Option, we also believe it is important to provide eligible clinicians as much information as possible about their QP status under the Medicare Option prior to the proposed All-Payer Information Submission Deadline, as subsequently discussed in section II.D.6.d.(4)(b) of this proposed rule. We therefore propose to inform eligible clinicians of their QP status under the All-Payer Combination Option as soon as practicable after the proposed All-Payer Information Submission Deadline.

(3) QP Determinations Under the All-Payer Combination Option

In the CY 2017 Quality Payment Program final rule, we finalized that, similar to the Medicare Option, we will calculate the Threshold Scores used to make QP determinations under the All-Payer Combination Option at the APM Entity group level unless certain exceptions apply (81 FR 77478).

(a) QP Determinations at the Individual Eligible Clinician Level

Upon further consideration, we propose to make QP determinations under the All-Payer Combination Option at the individual eligible clinician level only. We believe that there will likely be significant challenges associated with making QP determinations under the All-Payer Combination Option at the APM Entity group level as we finalized through rulemaking last year.

As we explained in the CY 2017 Quality Payment Program final rule, an APM Entity faces the risks and rewards of participation in an Advanced APM as a single unit and is responsible for performance metrics that are aggregated to the APM Entity group level as determined by the Advanced APM unless that APM Entity falls under the exception specified in § 414.1425(b)(1) for eligible clinicians on Affiliated Practitioner Lists. Because of this, we believe it is generally preferable to make QP determinations at the APM Entity level unless we are making QP determinations for eligible clinicians identified on Affiliated Practitioner Lists as specified at § 414.1425(b)(1); or we are making QP determinations for eligible clinicians participating in multiple APM Entities, none of which reach the QP Threshold as a group as specified at § 414.1425(c)(4) (81 FR 77439). However, under the All-Payer Combination Option, we believe in many instances that the eligible clinicians in the APM Entity group we would identify and use to make QP determinations under the Medicare Option would likely have little, if any, common group-level participation in Other Payer Advanced APMs. The eligible clinicians in the same APM Entity group would not necessarily have agreed to share risks and rewards for Other Payer Advanced APM participation as an APM Entity group, particularly when eligible clinicians may participate in Other Payer Advanced APMs at different rates within an APM Entity group (or not at all).

Eligible clinicians may participate in Other Payer Advanced APMs whose participants do not completely overlap, or do not overlap at all, with the APM Entity the eligible clinician is part of. Therefore, we believe that looking at participation in Other Payer Advanced APMs at the individual eligible clinician level may be a more meaningful way to assess their participation across multiple payers. In addition, those risks and rewards associated with participation in Other Payer Advanced APMs may vary significantly among eligible clinicians depending on the Other Payer Advanced APMs in which they participate. Specifically, we are concerned that if we were to make All-Payer Combination Option QP determinations at the APM Entity level, the denominator in QP threshold calculations could include all other payments and patients from eligible clinicians who had no, or limited, Other Payer Advanced APM participation, thereby disadvantaging those eligible clinicians who did have significant Other Payer Advanced APM participation. By contrast, this scenario is unlikely to occur when making QP determinations at the APM Entity level under the Medicare Option because all eligible clinicians in the APM Entity group would be contributing to the APM Entity's performance under the Advanced APM. For these reasons, we believe it would be most appropriate to make all QP determinations under the All-Payer Combination Option at the individual eligible clinician level.

We seek comment on this proposal, specifically on the possible extent to which APM Entity groups in Advanced APMs could agree to be assessed collectively for performance in Other Payer Advanced APMs. We also seek comment on whether there is variation, and the extent of that variation, among eligible clinicians within an APM Entity group in their participation in other payer arrangements that we may determine to be Other Payer Advanced APMs We seek comment on whether there are circumstances in which QP determinations should be made at a group level under the All-Payer Combination Option.

If we were to establish a mechanism for making QP determinations at the APM Entity group level, we anticipate that there could be significant challenges in obtaining the information necessary at the APM Entity group level under the All-Payer Combination

Option. When we make QP determinations at the APM Entity group level under the Medicare Option, we can do so more easily because we receive Participation Lists and we also have the claims data necessary to identify the payment or patient data that belong in the numerator and denominator of the Threshold Score calculations for QP Determinations.

To make QP determinations at the APM Entity group level under the All-Payer Combination Option, we would need to collect for each APM Entity group all of the payment amount and patient count information for all eligible clinicians as discussed in section II.D.6.d.(4)(a) of this proposed rule. We anticipate also needing Participation Lists or similar documentation to identify eligible clinicians within each APM Entity group that participate in an Other Payer Advanced APM. We seek comment on whether APM Entities in Other Payer Advanced APMs could report this information at the APM Entity group level to facilitate our ability to make QP determinations at the group level.

We note that when an Affiliated Practitioner List defines the eligible clinicians to be assessed for QP determination in the Advanced APM, we make QP determinations under the Medicare Option at the individual level only. To promote consistency with the Medicare Option where possible, if in response to comments on this proposed rule we adopt a mechanism to make QP determinations under the All-Payer Combination Option at the APM Entity group level, we propose that eligible clinicians who meet the criteria to be assessed individually under the Medicare Option would still be assessed at the individual level only under the All-Payer Combination Option. We seek comment on whether there are alternative approaches to making QP determinations under the All-Payer Combination Option for eligible clinicians who meet the criteria to be assessed individually under the Medicare Option.

(b) Use of Individual or APM Entity Group Information for Medicare Payment Amounts and Patient Count Calculations Under the All-Payer Combination Option

Because we are proposing to make QP determinations at the individual eligible clinician level only, we are proposing to use the individual eligible clinician payment amounts and patient counts for the Medicare calculations in the All-Payer Combination Option. We believe that matching the information we use at the same level for all payment amounts and patient counts for both the Medicare and all-payer calculations under the All-Payer Combination Option is most consistent with sections 1833(z)(2)(B)(ii) and (C)(ii) of the Act because these provisions require calculations that add together the payments or patients from Medicare and all other payers (except those excluded). We note however that we would use the APM Entity group level payment amounts and patient counts for all Medicare Option Threshold Scores, unless we are making QP determinations for Affiliated Practitioner Lists as specified at § 414.1425(b)(1) or we are making QP determinations for eligible clinicians participating in multiple APM Entities, none of which reach the QP Threshold as a group as specified at § 414.1425(c)(4) (81 FR 77439).

If we were to use the APM Entity group level payment amounts and patient counts for Medicare and individual eligible clinician payment amounts and patient counts for other payers, we would combine APM Entity group level Medicare information with individual eligible clinician level other payer information. In most instances this would disproportionately underweight the eligible clinicians' activities in Other Payer Advanced APMs relative to their activities in Advanced APMs when calculating Threshold Scores under the All-Payer Combination Option. We do not believe that this underweighting would be consistent with sections 1833(z)(2)(B)(ii) and (c)(11) of the Act.

We recognize that in many cases an individual eligible clinician's Medicare Threshold Scores would likely differ from Threshold Scores calculated at the APM Entity group level, which would benefit those eligible clinicians whose individual Threshold Scores would be higher than the group Threshold Scores and disadvantage those eligible clinicians whose individual Threshold Scores are equal to or lower than the group Threshold Scores. In situations where eligible clinicians are assessed under the Medicare Option as an APM Entity group, and receive a Medicare Threshold Score at the group level, we believe that the Medicare portion of their All-Payer Combination Option should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group.

To accomplish this outcome, we propose a modified methodology. When the eligible clinician's Medicare Threshold Score calculated at the individual level would be a lower percentage than the one that is calculated at the APM Entity group level we would apply a weighted methodology. This methodology would allow us to apply the APM Entity group level Medicare Threshold Score (if higher than the individual eligible clinician level Medicare Threshold Score), to the eligible clinician, under either the payment amount or patient count method, but weighted to reflect the individual eligible clinician's Medicare volume.

We would multiply the eligible clinician's APM Entity group Medicare Threshold Score by the total Medicare payments or patients made to that eligible clinician as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score} \times \textit{Clinician Medicare Payments or Patients}] + \textit{Individual Other Payer Advanced APM Payments or Patients}}{\textit{Individual Payments or Patients (All Payers except those excluded)}}$$

As an example of how this weighting methodology would apply under the payment amount method for payment year 2021, consider the following APM Entity group with two clinicians, one of whom participates in Other Payer Advanced APMs and one who does not.

TABLE 55—WEIGHTING METHODOLOGY EXAMPLE—PAYMENT AMOUNT METHOD

	Medicare—Advanced APM Payments	Medicare—Total Payments	Other Payer—Advanced APM Payments	Other Payer—Total Payments
Clinician A	$150	$200	$0	$500
Clinician B	150	800	760	1,200

TABLE 55—WEIGHTING METHODOLOGY EXAMPLE—PAYMENT AMOUNT METHOD—Continued

	Medicare—Advanced APM Payments	Medicare—Total Payments	Other Payer—Advanced APM Payments	Other Payer—Total Payments
APM Entity	300	1,000		

In this example, the APM Entity group Medicare Threshold Score is $300/$1000, or 30 percent. Eligible Clinicians A and B would not be QPs under the Medicare Option, but Clinician B could request that we make a QP determination under the All-Payer Combination Option since the APM Entity group exceeded the 25 percent minimum Medicare payment amount threshold under that option.

If we calculate Clinician B's payments individually as proposed, we would calculate the Threshold Score as follows:

$$\frac{\$150 + \$760}{\$800 + \$1200} = 46\%$$

Because Clinician B's Threshold Score is less than the 50 percent QP Payment Amount Threshold, Clinician B would not be a QP based on this result. However, if we apply the weighting methodology, we would calculate the Threshold Score as follows:

$$\frac{\left(\frac{\$300}{\$1000} \times \$800\right) + \$760}{\$800 + \$1{,}200} = 50\%$$

Based upon this Threshold Score, Clinician B would be a QP under the All-Payer Combination Option.

We would calculate the eligible clinician's Threshold Scores both individually and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. We seek comment on this approach.

(c) Title XIX Excluded Payments and Patients

Sections 1833(z)(2)(B)(ii)(I)(bb) and 1833(z)(2)(C)(ii)(I)(bb) of the Act direct us to exclude payments made under Title XIX in a state where no Medicaid Medical Home Model or Medicaid APM is available under that state program. To carry out this exclusion, in the CY 2017 Quality Payment Final Rule, we finalized that for both the payment amount and patient count methods, Title XIX payments or patients will be excluded from the numerator and denominator for the QP determination unless:

(1) A state has in operation at least one Medicaid APM or Medicaid Medical Home Model that is determined to be an Other Payer Advanced APM; and

(2) The relevant APM Entity is eligible to participate in at least one of such Other Payer Advanced APMs during the QP Performance Period, regardless of whether the APM Entity actually participates in such Other Payer Advanced APMs (81 FR 77475).

For purposes of the discussion below on the exclusion of Title XIX payments and patients in QP determinations, when we refer to Medicaid APMs or Medicaid Medical Home Models, we mean to refer to those that are Other Payer Advanced APMs. We also discussed that if a state operates such an Other Payer Advanced APM at a sub-state level such that eligible clinicians who do not practice in the area are not eligible to participate, Medicaid payments or patients should not be included in those eligible clinicians' QP calculations because no Medicaid Medical Home Model or Medicaid APM was available for their participation (81 FR 77475).

We propose that we will use the county level to determine whether a state operates a Medicaid APM or a Medicaid Medical Home Model at a sub-state level. We believe that the county level is appropriate as in our experience, the county level is the most common geographic unit used by states when creating payment arrangements under Title XIX at the sub-state level. We believe that applying this exclusion at the county level would allow us to carry out this exclusion in accordance with the statute in a way that would not penalize eligible clinicians who have no Medicaid APMs or Medicaid Medical Home Models available to them. We seek comment on this proposal.

We propose that, in states where a Medicaid APM or Medicaid Medical Home Model only exists in certain counties, we would exclude Title XIX data from an eligible clinician's QP calculations unless the county where the eligible clinician saw the most patients during the relevant All-Payer QP Performance Period was a county where a Medicaid APM or Medicaid Medical Home Model determined to be an Other Payer Advanced APM was available. We would require eligible clinicians to identify and certify the county where they saw the most patients during the relevant All-Payer QP Performance Period. If this county is not in a county where a Medicaid APM or Medicaid Medical Home Model was available during the All-Payer QP Performance Period, then Title XIX payments would be excluded from the eligible clinician's QP calculations. We are proposing this approach to ensure that, before including Title XIX payment or patient count information in calculating QP determinations, eligible clinicians have a meaningful opportunity to participate in a Medicaid APM or Medicaid Medical Home Model determined to be an Other Payer Advanced APM in a manner that would allow for both positive and negative contributions to their QP threshold score under the All-Payer Combination Option. We seek comments on this proposal.

As we discuss in section II.D.6.c.(3) of this proposed rule, we need to determine whether there are Medicaid APMs and Medicaid Medical Home Models available in each state prior to end of the All-Payer QP Performance Period in order to properly implement the statutory exclusion of Title XIX payments and patients, which is why we finalized in the CY 2017 Quality Payment Program final rule that we will identify Medicaid APMs and Medicaid Medical Home Models that are Other Payer Advanced APMs prior to the QP Performance Period (81 FR 77478).

In addition to excluding payments based on county-level geography, we propose to exclude Title XIX payments and patients from the QP determination calculation when the only Medicaid APMs and Medicaid Medical Home Models available in a given county are not available to the eligible clinician in question based on their specialty. We believe that this proposal is consistent with the statutory requirement to exclude Title XIX data from the calculations when no Medicaid APM or Medicaid Medical Home Model is available. In cases where participation in such a model is limited to eligible clinicians in certain specialties, we do not believe the Medicaid APM or Medicaid Medical Home Model would effectively be available to eligible

clinicians who are not in those specialties. We therefore believe it would be inappropriate and inequitable to include Title XIX payments and patients in such eligible clinicians' QP determination calculations. We propose to identify Medicaid APM or Medicaid Medical Home Models that are only open to certain specialties through questions asked of states in the Payer Initiated Process and of APM Entities and eligible clinicians in the Eligible Clinician Initiated Process. We would exclude Title XIX data from an eligible clinician's QP calculations unless the eligible clinician practiced under one of the specialty codes eligible to participate in a Medicaid APM or Medicaid Medical Home Model that was available in the county where the eligible clinician saw the most patients. We would use the method generally used in the Quality Payment Program to identify an eligible clinician's specialty or specialties. We seek comment on this proposal.

We also wish to clarify that payment arrangements offered by Medicare-Medicaid Plans, operating under the Financial Alignment Initiative for Medicare-Medicaid Enrollees, will not be considered to be either Medicaid APMs or Medicaid Medical Home Models, and that the presence of such payment arrangements in a state will not preclude the exclusion of Title XIX payment and patients in the All-Payer Combination Option calculations for eligible clinicians in that state if no Medicaid APM or Medicaid Medical Home Model is otherwise in operation in the state. Medicare-Medicaid Plans are limited to certain Medicare-Medicaid enrollees, and enter into payment arrangements that do not uniformly segregate Title XVIII and Title XIX funds. As such, payments to eligible clinicians in Medicare-Medicaid plans cannot consistently be attributed to funding under either Title XVIII or XIX. Additionally, given that Medicare is generally the primary payer for services furnished by eligible clinicians to dual Medicare-Medicaid enrollees, any possible segregable Title XIX funding for professional services through these payment arrangements would be de minimus. We do not believe it would be appropriate to consider these payment arrangements exclusively focused on this population as Medicaid APMs or Medicaid Medical Home Models.

(d) Payment Amount Method

In the CY 2017 Quality Payment Program final rule, we finalized that we will calculate an All-Payer Combination Option Threshold Score for eligible clinicians in an APM Entity using the payment amount method (81 FR 77476 through 77477). We finalized that the numerator will be the aggregate of all payments from all payers, except those excluded, to the APM Entity's eligible clinicians, or the eligible clinician in the event of an individual eligible clinician assessment, under the terms of all Other Payer Advanced APMs during the QP Performance Period. We finalized that the denominator will be the aggregate of all payments from all payers, except excluded payments, to the APM Entity's eligible clinicians, or the eligible clinician in the event of an individual eligible clinician assessment during the QP Performance Period.

We finalized that we will calculate the Threshold Score by dividing the numerator value by the denominator value, which will result in a percent value Threshold Score. We will compare that Threshold Score to the finalized QP Payment Amount Threshold and the Partial QP Payment Amount Threshold and determine the QP status of the eligible clinicians for the payment year (81 FR 77475).

We propose to maintain the policies we finalized for the payment amount method as finalized, with some proposed modifications. We propose these changes to facilitate the implementation of the payment amount method while providing eligible clinicians with some flexibility in choosing the timeframe for making QP determinations. To carry out our proposal to make QP determinations at the eligible clinician level only, we propose that the numerator would be the aggregate of all payments from all payers, except those excluded, attributable to the eligible clinician only, under the terms of all Advanced APMs and Other Payer Advanced APMs from either January 1 through March 31 or January 1 through June 30 of the All-Payer QP Performance Period. We also propose that the denominator would be the aggregate of all payments from all payers, except excluded payments, to the eligible clinician from either January 1 through March 31, or January 1 through June 30 of the All-Payer QP Performance Period. We seek comment on this approach.

(e) Patient Count Method

We finalized that the Threshold Score calculation for the patient count method would include patients for whom the eligible clinicians in an APM Entity furnish services and receive payment under the terms of an Other Payer Advanced APM, except for those that are excluded (81 FR 77477 through 77478). We finalized that the numerator would be the number of unique patients to whom eligible clinicians in the APM Entity furnish services that are included in the aggregate expenditures used under the terms of all their Other Payer Advanced APMs during the QP Performance Period plus the patient count numerator for Advanced APMs (81 FR 77477 through 77478). We finalized that the denominator would be the number of unique patients to whom eligible clinicians in the APM Entity furnish services under all payers, except those excluded (81 FR 77477 through 77478). We finalized that we will calculate the Threshold Score by dividing the numerator value by the denominator value, which will result in a percent value Threshold Score (81 FR 77477 through 77478). We will compare that Threshold Score to the finalized QP Patient Count Threshold and the Partial QP Patient Count Threshold and determine the QP status of the eligible clinicians for the payment year (81 FR 77477 through 77478). We finalized that we would count each unique patient one time in the numerator and one time in the denominator (81 FR 77477 through 77478).

We intend to carry out QP determinations using the patient count method as finalized with some proposed modifications. We propose these changes to facilitate the implementation of the patient count method while providing eligible clinicians with some flexibility in choosing the timeframe for making QP determinations. To carry out our proposal to make QP determinations at the eligible clinician level only, we propose to count each unique patient one time in the numerator and one time in the denominator across all payers to align with our finalized policy for patient counts at the eligible clinician level. We propose that the numerator would be the number of unique patients the eligible clinician furnishes services to under the terms of all of their Advanced APMs or Other Payer Advanced APMs from either January 1 through March 31, or January 1 through June 30 of the All-Payer QP Performance Period. We propose that the denominator would be the number of unique patients the eligible clinician furnishes services to under all payers, except those excluded from either January 1 through March 31, or January 1 through June 30 of the All-Payer QP Performance Period. We seek comment on this approach.

(4) Submission of Information for QP Determinations Under the All-Payer Combination Option

In the CY 2017 Quality Payment Program final rule, we finalized that

either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). We also finalized that if we do not receive sufficient information to complete our evaluation of an other payer arrangement and to make QP determinations, we would not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

(a) Required Information

In order for us to make QP determinations for an eligible clinician under the All-Payer Combination Option, we need information for all of the Other Payer Advanced APMs in which an eligible clinician participated during the All-Payer QP Performance Period. Eligible clinicians can participate in other payer arrangements that we determine are Other Payer Advanced APMs through the Payer Initiated Process, through the Eligible Clinician Initiated Process, or both. We discuss the submission of information that pertains to Other Payer Advanced APM determinations in section II.D.6.c.(7)(a) of this proposed rule.

In order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we would need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the All-Payer QP Performance Period. We clarify that eligible clinicians will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option.

To make calculations for the snapshot dates as proposed in section II.D.6.d.(4)(b) of this proposed rule, we will need this payment amount and patient count information from January 1 through June 30 of the calendar year 2 years prior to the payment year. We will need this payment amount and patient count information submitted in a way that allows us to distinguish information from January 1 through March 31 and from January 1 through June 30 so that we can make QP determinations based on the two snapshot dates as discussed above.

To meet the need for information in a way that we believe minimizes reporting burden, we propose to collect this payment amount and patient count information aggregated for the two proposed snapshot time frames: From January 1 through March 31 and from January 1 through June 30. We seek comment on this approach, particularly as to the feasibility of submitting information in this way and suggestions on how to further minimize reporting burden. Alternatively, if we finalize an All-Payer QP Performance Period of January 1 through March 31, we would need payment amount and patient count information only from January 1 through March 31. If we retain the current finalized QP Performance Period, we would need information aggregated for three snapshot timeframes: From January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As we discuss in section II.D.6.d.(3)(a) of this proposed rule, we are proposing to make QP determinations under the All-Payer Combination Option only at the eligible clinician level. As a result, we propose that all of this payment and patient information must be submitted at the eligible clinician level, and not at the APM Entity group level as we finalized in rulemaking last year.

To minimize reporting burden on individual eligible clinicians and to allow eligible clinicians to submit information to us as efficiently as possible, we propose to allow eligible clinicians to have APM Entities submit this information on behalf of any of the eligible clinicians in the APM Entity group at the individual eligible clinician level. We seek comments on these proposals, particularly regarding the feasibility of APM Entities reporting this information for some or all of the eligible clinicians in the APM Entity group.

Additionally, we propose that if an APM Entity or eligible clinician submits sufficient information only for the payment amount or patient count method, but not for both, we will make a QP determination based on the one method for which we receive sufficient information. We believe that this proposal is consistent with our overall approach, particularly because we have finalized that we will use the more advantageous of the Threshold Scores to make QP determinations (81 FR 77475). We clarify that APM Entities or eligible clinicians can submit information to allow us to use both the payment amount and patient count methods.

To facilitate and ease burden for information submissions, we also propose to create a form that APM Entities or eligible clinicians would be able to use to submit this payment amount and patient count information. APM Entities and eligible clinicians would be required to use this form for submitting the payment and patient information.

We seek comment on these proposals.

(b) QP Determination Submission Deadline

We propose that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline.

We believe that December 1 is the latest date in the year that we could receive information, and be able to complete QP determinations and notify eligible clinicians of their QP status in time for them to report to MIPS as needed. We also proposed this date for the QP Determination Submission Deadline to provide eligible clinicians requesting QP determinations under the All-Payer Combination Option as much time as possible to gather and submit information.

In the CY 2017 Quality Payment Program final rule, we finalized that without sufficient information we will not make QP determinations under the All-Payer Combination Option (81 FR 77480). As such, we will not make QP determinations for an eligible clinician under the All-Payer Combination Option if we do not receive information sufficient to make a QP determination under either the payment amount or patient count method by the QP Determination Submission Deadline.

We seek comment on these proposals.

(c) Certification and Program Integrity

We propose that a new requirement be added at § 414.1440(f)(2) stating that the APM Entity or eligible clinician that submits information to request a QP

determination under the All-Payer Combination Option must certify to the best of its knowledge that the information that they submitted to us is true, accurate, and complete. In the case of information submitted by the APM Entity, we propose that the certification must be made by an individual with the authority to legally bind the APM Entity. This certification would accompany the Eligible Clinician Initiated Submission Form, which both eligible clinicians and APM Entities use for the Eligible Clinician Initiated Process. We seek comment on these proposals.

We propose to revise the monitoring and program integrity provisions at § 414.1460 to further promote the integrity of the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1460(e) that an APM Entity or eligible clinician that submits information to us under § 414.1445 for assessment under the All-Payer Combination Option must maintain such books contracts records, documents, and other evidence for a period of 10 years from the final date of the QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later (81 FR 77555). We also finalized at § 414.1460(c) that eligible clinicians and APM Entities must maintain copies of any supporting documentation related to the All-Payer Combination Option for at least 10 years (81 FR 77555). We propose to revise § 414.1460(e) to apply to information submitted to us under § 414.1440 for QP determinations. We also propose to add paragraph (3) to § 414.1460(e) stating that an APM Entity or eligible clinician who submits information to us under § 414.1445 or § 414.1440 must provide such information and supporting documentation to us upon request. We seek comments on these proposals.

(d) Use of Information

In the CY 2017 Quality Payment Program final rule, we finalized that, to the extent permitted by federal law, we will maintain confidentiality of the information and data that APM Entities and eligible clinicians submit to support Other Payer Advanced APM determinations in order to avoid dissemination of potentially sensitive contractual information or trade secrets (81 FR 77479 through 77480).

We believe that it is similarly appropriate for us to maintain the confidentiality of information submitted to us for the purposes of QP determinations to the extent permitted by federal law. Therefore, we propose that, to the extent permitted by federal law, we will maintain confidentiality of the information that APM Entities or eligible clinicians submit to us for purposes of QP determinations under the All-Payer Combination Option, in order to avoid dissemination of potentially sensitive contractual information or trade secrets.

(5) Example

In Tables 56 and 57, we provide examples where an eligible clinician is in a Medicare ACO Model that we have determined to be an Advanced APM, a commercial ACO arrangement, and a Medicaid APM from January 1 through June 30, 2019. We would use the information below to determine that eligible clinician's QP status for payment year 2021.

We would calculate the Threshold Scores for the APM Entity group in the Advanced APM under the Medicare Option. For the payment amount method, as shown in Table 56, the APM Entity group would not attain QP status under the Medicare Option, which for payment year 2021 requires a QP payment amount Threshold Score of 50 percent. The APM Entity group would also fail to attain Partial QP status under the Medicare Option, which for payment year 2021 requires a Partial QP payment amount Threshold Score of 40 percent. For the patient count method, as shown in Table 57, the APM Entity group would not attain QP status under the Medicare Option, which for payment year 2021 requires a QP patient count Threshold Score of 35 percent. The APM Entity group would not attain Partial QP status under the Medicare Option, which for payment year 2021 requires a Partial QP patient count Threshold Score of 25 percent.

TABLE 56—ALL-PAYER COMBINATION OPTION EXAMPLE—PAYMENT AMOUNT METHOD

Payer	Level	Payments to group/eligible clinician by payer (in dollars)	Total payments to group/eligible clinician by payer (in dollars)	Threshold score (percentage)
Medicare Option				
Advanced APM (Medicare)	APM Entity Group	300,000	1,000,000	30
All-Payer Combination Option				
Advanced APM (Medicare)	Eligible Clinician	20,000	50,000	
Other Payer Advanced APM (Commercial)	Eligible Clinician	20,000	50,000	
Medicaid APM	Eligible Clinician	80,000	100,000	
Totals for All-Payer Combination Option	Eligible Clinician	120,000	200,000	60

TABLE 57—ALL-PAYER COMBINATION OPTION EXAMPLE—PATIENT COUNT METHOD

Payer	Level	Patients of group/eligible clinician by payer	Total patients of group/eligible clinician by payer	Threshold score (percentage)
Medicare Option				
Advanced APM (Medicare)	APM Entity Group	2,200	10,000	22

TABLE 57—ALL-PAYER COMBINATION OPTION EXAMPLE—PATIENT COUNT METHOD—Continued

Payer	Level	Patients of group/eligible clinician by payer	Total patients of group/eligible clinician by payer	Threshold score (percentage)
All-Payer Combination Option				
Advanced APM (Medicare)	Eligible Clinician	200	1,000	
Other Payer Advanced APM (Commercial)	Eligible Clinician	100	500	
Medicaid APM	Eligible Clinician	500	1,000	
Totals for All-Payer Combination Option	Eligible Clinician	800	2,500	32

The APM Entity group did not attain QP or Partial QP status under either the payment amount or patient count method under the Medicare Option. However, because under both methods of calculation, the APM Entity group meets or exceeds the required Medicare threshold for the year under the All-Payer Combination Option of 25 percent and 20 percent, respectively, eligible clinicians within the APM Entity group would be eligible to obtain QP status through the All-Payer Combination Option. The eligible clinicians in the APM Entity group would have been notified of this as we share information on a regular basis on their QP status under each snapshot. For payment year 2021, the eligible clinicians in this APM Entity group would submit their payment amount or patient count data from all payers to calculate their Threshold Score under the All-Payer Combination Option.

In this example, the eligible clinician score exceeds the QP payment amount Threshold under the All-Payer Combination Option, which for payment year 2021 is 50 percent, but the eligible clinician only exceeds the Partial QP patient count Threshold under the All-Payer Combination Option, which for payment year 2021 is 40 percent. We would use the more advantageous score, so the eligible clinician would be a QP for payment year 2021.

Alternatively, if we were to use the APM Entity weighted methodology for calculation of a Threshold Score using the payment amount method as described in section II.D.6.d.(3)(d) of this proposed rule, we would apply the weighting methodology as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score} \times \textit{Clinician Medicare Payments or Patients}] + \textit{Individual Other Payer Advanced APM Payments or Patients}}{\textit{Individual Payments or Patients (All Payers except those excluded)}}$$

$$\frac{\left(\frac{\$300,000}{\$1,000,000} \times \$50,000\right) + \$100,000}{\$50,000 + \$150,000} = 58\%$$

The eligible clinician would obtain a Threshold Score of 58 percent. This would be slightly below the Threshold Score obtained from the individual eligible clinician payment count calculation, but it would still exceed the QP payment amount Threshold of 50 percent under the All-Payer Combination Option. Based upon this Threshold Score, the eligible clinician would be a QP under the All-Payer Combination Option.

(6) Partial QP Election To Report to MIPS

In the 2017 Quality Payment Program final rule, we finalized under the Medicare Option that, in the cases where the QP determination is made at the individual eligible clinician level, if the eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report to MIPS and then be subject to MIPS reporting requirements and payment adjustments (81 FR 77449). To promote alignment with the Medicare Option and to simplify requirements when possible, we propose that eligible clinicians who are Partial QPs for the year under the All-Payer Combination Option would make the election whether to report to MIPS and then be subject to MIPS reporting requirements and payment adjustments. We seek comment on this approach.

(7) Summary Proposals

To summarize, we are proposing the following:

- We propose to establish the All-Payer QP Performance Period, which would begin on January 1 and end on June 30 of the calendar year that is 2 years prior to the payment year.
- We propose to make QP determinations based on eligible clinicians' participation in Advanced APMs and Other Payer Advanced APMs for two time periods: Between January 1 through March 31 and between January 1 through June 30 of the All-Payer QP Performance Period under the All-Payer Combination Option. We propose to use data for the same time periods for Medicare payments or patients and that of other payers. We also propose the eligible clinicians must request QP determinations under the All-Payer Combination Option and must submit to CMS payment amount and patient count data from other payers to support the determination.
- We propose to notify eligible clinicians of their QP status under the All-Payer Combination Option as soon as practicable after the proposed QP Determination Submission Deadline.
- We propose to make QP determinations under the All-Payer Combination Option at the individual eligible clinician level only.
- We propose to use the individual eligible clinician payment amounts and patient counts for Medicare in the All-

Payer Combination Option. We propose that when the eligible clinician's Medicare Threshold Score calculated at the individual level would be a lower percentage than the one that is calculated at the APM Entity group level, we would apply a weighted methodology.

- We propose that we will determine whether a state operates a Medicaid APM or a Medicaid Medical Home Model that has been determined to be an Other Payer Advanced APM at a sub-state level. We propose that we will use the county level to determine whether a state operates a Medicaid APM or a Medicaid Medical Home Model an Other Payer Advanced APM at a sub-state level.
- We propose that in a state where we determine there are one or more Medicaid APMs or Medicaid Medical Home Models that are Other Payer Advanced APMs in operation, but only in certain counties, or only for eligible clinicians in certain specialties, we would further evaluate whether those Medicaid APMs or Medicaid Medical Home Models were available to each eligible clinician for whom we make a QP determination under the All-Payer Combination Option. We would identify the county in which the eligible clinician practices by having the eligible clinician submit that information to identify the county where they saw the most patients during the relevant All-Payer QP Performance Period when they request a QP determination. We also propose that if the eligible clinician's practice is in a county, or in a specialty, in which there is no Medicaid APM or Medicaid Medical Home Model in operation, all of that eligible clinician's Medicaid payments and patients would be excluded from the numerator and denominator of the calculations under the payment amount or patient count method, respectively. We also propose to identify Medicaid APM or Medicaid Medical Home Models that are only open to certain specialties through questions asked of states in the Payer Initiated Process and of eligible clinicians in the Eligible Clinician Initiated Process. We would use the method generally used in the Quality Payment Program to identify an eligible clinician's specialty or specialties.
- For the payment amount method we would first make a calculation under the Medicare Option using all Medicare payments for the APM Entity. If the minimum threshold score for the Medicare Option were met, we would make calculations under the All-Payer Combination Option. We propose that under the All-Payer Combination Option the numerator would be the aggregate of all payments from all payers, except those excluded, that are made or attributable to the eligible clinician, under the terms of all Advanced APMs and Other Payer Advanced APMs. We also propose that the denominator would be the aggregate of all payments from all payers, except those excluded, that are made or attributed to the eligible clinician.
- For the patient count method under the All-Payer Combination Option, we propose to count each unique patient one time in the numerator and one time in the denominator across all payers to align with our finalized policy for patient counts at the eligible clinician level. We propose that the numerator would be the number of unique patients the eligible clinician furnishes services to under the terms of all of their Advanced APMs or Other Payer Advanced APMs. We propose that the denominator would be the number of unique patients the eligible clinician furnishes services to under all payers, except those excluded.
- We propose to collect the necessary payment amount and patient count information for QP determinations under the All-Payer Combination Option aggregated for the two proposed snapshot timeframes: From January 1 through March 31 and from January 1 through June 30. We propose that APM Entities may submit this information on behalf of any of the eligible clinicians in the APM Entity group at the individual eligible clinician level.
- We propose that if an APM Entity or eligible clinician submits sufficient information for either the payment amount or patient count method, but not for both, we will make a QP determination based on the one method for which we receive sufficient information.
- We propose that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline.
- We propose that an APM Entity or eligible clinician who submits information to request a QP determination under the All-Payer Combination Option must certify to the best of its knowledge that the information submitted is true, accurate and complete. In the case of information submitted by the APM Entity, we propose that the certification be made by an executive of the APM Entity. We also propose that this certification must accompany the form that APM Entities or eligible clinicians submit to us when requesting that we make QP determinations under the All-Payer Combination Option.
- We propose that APM Entities and eligible clinicians that submit information to CMS under § 414.1445 for assessment under the All-Payer Combination Option or § 414.1440 for QP determinations must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determinations, and the accuracy of APM Incentive Payments for a period of 10 years from the end of the All-Payer QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later.
- We propose that APM Entities and eligible clinicians that submit information to us under § 414.1445 or § 414.1440 must provide such information and supporting documentation to us upon request.
- We propose that, to the extent permitted by federal law, we will maintain confidentiality of the information that an APM Entity or eligible clinician submits to us for purposes of QP determinations under the All-Payer Combination Option, to avoid dissemination of potentially sensitive contractual information or trade secrets.
- We propose that eligible clinicians who are Partial QPs for the year under the All-Payer Combination Option would make the election whether to report to MIPS and then be subject to MIPS reporting requirements and payment adjustments.

We seek comment on these proposals.

7. Physician-Focused Payment Models (PFPMs)

a. Overview

Section 1868(c) of the Act established an innovative process for individuals and stakeholder entities (stakeholders) to propose physician-focused payment models (PFPMs) to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The PTAC, established under section 1868(c)(1)(A) of the Act, is a federal advisory committee comprised of 11 members that provides advice to the Secretary. A copy of the PTAC's charter, established on January 5, 2016, is available at *https://aspe.hhs.gov/charter-physician-focused-payment-model-technical-advisory-committee*.

Section 1868(c)(2)(C) of the Act requires the PTAC to review stakeholders' proposed PFPMs, prepare comments and recommendations regarding whether such proposed PFPMs meet the PFPM criteria established by the Secretary, and submit those comments and recommendations to the Secretary. Section 1868(c)(2)(D) of the Act requires the Secretary to review the PTAC's comments and recommendations on proposed PFPMs and to post ''a detailed response'' to those comments and recommendations on the CMS Web site.

b. Definition of PFPM

(1) Definition of PFPM

In the CY 2017 Quality Payment Program final rule (81 FR 77555), we defined PFPM at § 414.1465 as an Alternative Payment Model in which: Medicare is a payer; eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Act are participants and play a core role in implementing the APM's payment methodology; and the APM targets the quality and costs of services that eligible clinicians participating in the Alternative Payment Model provide, order, or can significantly influence.

In the CY 2017 Quality Payment Program final rule (81 FR 77496) we finalized the requirement that PFPMs be tested as APMs with Medicare as a payer. We stated that a PFPM could include other payers in addition to Medicare, but that other payer arrangements and Other Payer Advanced APMs are not PFPMs. Therefore, PFPM proposals would need to include Medicare as a payer.

In this proposed rule, we seek comment on whether to broaden the definition of PFPM to include payment arrangements that involve Medicaid or the Children's Health Insurance Program (CHIP) as a payer, even if Medicare is not included as a payer. A PFPM would then include Medicaid, CHIP, or Medicare (or some combination of these) as a payer. A PFPM might still include other payers in addition to Medicaid, CHIP, or Medicare; however, an other payer arrangement or Other Payer Advanced APM that includes only private payers, including a Medicare Advantage plan, would not be a PFPM. Medicare Advantage and other private plans paid to act as insurers on the Medicare program's behalf are considered to be private payers. The inclusion of Medicaid or CHIP as a payer would not imply the waiver of any requirements under Title XIX or Title XXI; PFPMs with Medicaid or CHIP as a payer would be required to follow all applicable regulations and requirements relevant to the approach they propose except those for which waivers are expressly provided under the terms of the PFPM in the event, and at the time, that the PFPM is implemented.

We believe broadening the definition of PFPM to include payment arrangements with Medicaid and CHIP, even if Medicare is not included in the payment arrangement, may complement the policies we are proposing within this rule for the All-Payer Combination Option. Broadening the definition of PFPM could potentially provide an opportunity for stakeholders to propose PFPMs to the PTAC that could be Other Payer Advanced APMs, and participation in such Other Payer Advanced APMs would contribute to an eligible clinician's ability to become a QP through the All-Payer Combination Option.

The PTAC's charge is to review submitted proposals and provide comments and recommendations to the Secretary regarding whether the proposals meet the PFPM criteria established by the Secretary. The Secretary is then charged with reviewing and posting on the CMS Web site a detailed response to the PTAC's comments and recommendations.

Because the Secretary does not have authority to direct the design or development of payment arrangements that might be tested with private payers, we seek comment on, if we were to broaden the definition of PFPM, including in the scope of PFPMs only payment arrangements or models for which the Secretary and CMS could take subsequent action following the statutory PTAC review process.

We seek comment on whether broadening the definition of PFPMs would be inclusive of potential PFPMs that could focus on areas not generally applicable to the Medicare population, such as pediatric issues or maternal health and whether changing the definition of PFPM may engage more stakeholders in designing PFPMs that include more populations beyond Medicare FFS beneficiaries. We seek comment on how the PFPM criteria could be applied to these payment arrangements. We seek comment on whether including more issues and populations fits within the PTAC's charge and whether stakeholders are interested in the opportunity to allow the PTAC to apply its expertise to a broader range of proposals for PFPMs.

The current definition of PFPM specifies that a PFPM is an APM. In the CY 2017 Quality Payment Program final rule (81 FR 77406), we noted that APM is defined under section 1833(z)(3)(C) of the Act as any of the following: (1) A model under section 1115A of the Act (other than a health care innovation award); (2) the Shared Savings Program under section 1899 of the Act; (3) a demonstration under section 1866C of the Act; or (4) a demonstration required by federal law. If a payment arrangement is a PFPM it must also be an APM. Under our current regulation, a model that does not meet the definition of APM is not a PFPM. However, a payment arrangement with Medicaid or CHIP as the payer, but not Medicare, would not necessarily meet the definition of APM. Therefore, we seek comment on whether we should, in tandem with potentially broadening the scope of PFPMs to include payment arrangements with Medicaid and CHIP, require that a PFPM be an APM or a payment arrangement operated under legal authority for Medicaid or CHIP payment arrangements.

In the CY 2017 Quality Payment Program final rule (81 FR 77494), we stated that we anticipate PFPMs that are recommended by the PTAC and tested by CMS will be tested using section 1115A authority, although a model or payment arrangement does not need to be tested under section 1115A of the Act to be a PFPM. APMs tested under sections 1115A or 1866C of the Act, or demonstrations required by federal law, may include Medicaid or CHIP, but not necessarily Medicare, as a payer. We believe that because Medicaid and CHIP payment arrangements may be operated under other legal authorities than those included in the definition of APM, such as section 1115(a) waivers, section 1915(b) and (c) waivers, and state plan amendments, we may need to consider broadening the PFPM definition beyond APMs to correspond with potentially including Medicaid or CHIP as the only payer. We note that were our policy to change, PFPMs that are Medicaid or CHIP payment arrangements that fall outside the definition of APM would need to follow the processes and meet the requirements associated with the legal authorities on which they are based.

We believe it is important for PFPMs to include innovative payment methodologies. For that reason, we continue to believe that the definition of PFPM, as well as the PFPM criteria we established through rulemaking should apply exclusively to payment arrangements, and not to arrangements focused on care delivery reform without a payment reform component. We believe there are various statutory authorities outside of those specified in the definition of APM that might allow

Medicaid and CHIP payment arrangements to be structured to address payment reform. We seek comment on whether states and stakeholders see value in having the definition of PFPM broadened to include payment arrangements with Medicaid or CHIP but not Medicare as a payer, and whether they see value in having proposals for PFPMs with Medicaid or CHIP but not Medicare as a payer go through the PTAC's review process.

(2) Relationship Between PFPMs and Advanced APMs

Section 1868(c) of the Act does not require PFPMs to meet the criteria to be an Advanced APM for purposes of the incentives for participation in Advanced APMs under section 1833(z) of the Act, and we did not define PFPMs solely as Advanced APMs. Stakeholders may therefore propose as PFPMs either Advanced APMs or Medical Home Models, or other APMs. If we were to broaden the definition to include payment arrangements with Medicaid or CHIP but not Medicare as a payer, stakeholders could propose as PFPMs Medicaid APMs, Medicaid Medical Home Models, or other payer arrangements involving Medicaid or CHIP as a payer. We recognize that both stakeholders and the PTAC may want to discuss whether a proposed PFPM would be an Advanced APM in their proposals, comments, and recommendations.

c. PTAC Review Process of PFPM Proposals With Medicaid or CHIP as a Payer

In the CY 2017 Quality Payment Program final rule (81 FR 77491 through 77492), we described the roles of the Secretary, the PTAC, and CMS as they relate to PFPMs and the PTAC's review process. We believe that expanding the definition of PFPM to include Medicaid or CHIP as a payer, even when Medicare is not involved, might encourage innovation in additional areas and that stakeholders and states may benefit from the PTAC's review process.

We intend to continue to give serious consideration to proposed PFPMs recommended by the PTAC. Section 1868(c) of the Act does not require us to test proposals that are recommended by the PTAC. In the CY 2017 Quality Payment Program final rule (81 FR 77491), we explained that without being able to predict the volume, quality, or appropriateness of the proposed PFPMs on which the PTAC will make comments and recommendations, we are not in a position to commit to test all such models. We continue to believe this is the case. In addition, we acknowledge that any PFPMs with Medicaid or CHIP as a payer, as we are seeking comment on, could not be tested without significant coordination and cooperation with the state(s) involved. We could not ensure the agreement of the state(s) for which a PFPM is proposed with Medicaid or CHIP as a payer, and therefore, similar to models with Medicare as the payer, we could not commit to testing these proposed payment arrangements. The Secretary and CMS must retain the ability to make final decisions on which PFPMs, whether they include Medicare as a payer or only include Medicaid or CHIP, are tested using section 1115A or section 1866C authority, and if so, when they are tested. Proposed PFPMs that the PTAC recommends to the Secretary but that are not immediately tested by us may be considered for testing at a later time.

We also could not speak to the length of time it would take a state to implement a PFPM with Medicaid or CHIP as a payer, or whether it would be shorter than the normal process for implementing a payment arrangement using Title XIX, Title XXI, or any other relevant legal authority.

The decision to test a model recommended by the PTAC that includes Medicare, Medicaid, or CHIP as a payer and is tested under section 1115A authority would not require submission of a second proposal to us; we would review the proposal submitted to the PTAC along with comments from the PTAC and the Secretary, and any other resources we believe would be useful. In order to further evaluate or proceed to test a proposed PFPM based on a recommendation from the PTAC under section 1115A authority, we may seek to obtain additional information based on the contents of the proposal. After a PFPM proposal has been recommended by the PTAC, if it is selected for further evaluation or testing under section 1115A authority, we may work with the individual stakeholders who submitted their proposals to consider design elements for testing the PFPM and make changes as necessary, to the extent that we are involved in the design and testing or operation of the PFPM. We note that if a PFPM we select for testing under section 1115A authority requires those interested to apply in order to participate, the stakeholder who submitted the proposal for a model to be established would still have to apply in order to participate in that model. PFPMs with Medicaid or CHIP as a payer operated under legal authority other than 1115A would need to meet the requirements for that legal authority.

We believe that proposed PFPMs that include Medicare as a payer and that meet all of the PFPM criteria and are recommended by the PTAC may need less time to go through the development process; however, we cannot guarantee that the development process would be shortened, or estimate by how much it would be shortened. These processes depend on the nature of the PFPM's design, and any attempt to impose a deadline on them would not benefit stakeholders because it would not allow us to tailor the review and development process to the needs of the proposed PFPM. We could not speak to the length of time it would take a state to implement a PFPM with Medicaid or CHIP as a payer, or whether it would be shorter than the normal process. This would be true for Medicaid or CHIP payment arrangements tested using any legal authorities.

d. PFPM Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77496), we finalized the Secretary's criteria for PFPMs as required by section 1868(c)(2)(A) of the Act. The PFPM criteria are for the PTAC's use in discharging its duties under section 1868(c)(2)(C) of the Act to make comments and recommendations to the Secretary on proposed PFPMs.

We seek comment on the Secretary's criteria, including, but not limited to, whether the criteria are appropriate for evaluating PFPM proposals and are clearly articulated. In addition, we seek comment on stakeholders' needs in developing PFPM proposals that meet the Secretary's criteria. In particular, we want to know whether stakeholders believe there is sufficient guidance available on what constitutes a PFPM, the relationship between PFPMs, APMs, and Advanced APMs; and on how to access data, or how to gather supporting evidence for a PFPM proposal.

e. Summary

In summary, we seek comment on changing the definition of PFPM to include payment arrangements with Medicare, Medicaid or CHIP, or any combination of these, as a payer; and we seek comment on revising the definition to require that a PFPM be an APM or a payment arrangement operated under legal authority for Medicaid or CHIP payment arrangements. We also seek comments on the Secretary's criteria more broadly and stakeholders' needs in developing PFPM proposals that meet the Secretary's criteria.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our 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 required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

Summary and Overview

The Quality Payment Program aims to do the following: (1) Support care improvement by focusing on better outcomes for patients, decreased clinician burden, and preservation of independent clinical practice; (2) promote adoption of alternative payment models that align incentives across healthcare stakeholders; and (3) advance existing delivery system reform efforts, including ensuring a smooth transition to a healthcare system that promotes high-value, efficient care through unification of CMS legacy programs.

The CY 2017 Quality Payment Program final rule established policies to implement MIPS, a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the PQRS, the VM, and the Medicare EHR Incentive Program for eligible professionals. As prescribed by MACRA, MIPS focuses on the following: Quality—including a set of evidence-based, specialty-specific standards; cost; practice-based improvement activities; and use of CEHRT to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies.

In the CY 2017 Quality Payment Program final rule, we estimated a reduction in burden hours of 1,066,658 and reduction of burden costs of $7.4 million relative to the legacy programs it replaced (81 FR 77513). The total existing burden for the previously approved information collections related to the CY 2017 Quality Payment Program final rule was approximately 11 million hours and a total labor cost of reporting of $1.311 million. The streamlining and simplification of data submission structures in the transition year resulted in a reduction in burden relative to the approved information collections for the legacy programs (PQRS and EHR Incentive Program for Eligible Professionals), which represented approximately 12 million hours for a total labor cost of reporting of $1.318 million. We estimate that the policies proposed in this rule would result in further reduction of 132,620 burden hours and a further reduction in burden cost of $12.4 million relative to a baseline of continuing the policies in the CY 2017 Quality Payment Program final rule. The Quality Payment Program Year 2 reduction in burden based on this rule reflects several proposed policies, including our proposal for significant hardship or other type of exception, including a new significant hardship exception for small practices for the advancing care information performance category; our proposal to use a shorter version of the CAHPS for MIPS survey; our proposal to allow election of facility-based measurement for applicable MIPS eligible clinicians, thereby eliminating the need for additional quality data submission processes; and our proposal to allow MIPS eligible clinicians to form virtual groups which would create efficiencies in data submission.

In addition to the decline in burden due to the policies proposed in this rule, we anticipate further reduction in burden as a result of policies set forth in the CY 2017 Quality Payment Program final rule, including greater clinician familiarity with the measures and data submission methods set in their second year of participation, operational improvements streamlining registration and data submission, and continued growth in the number of QPs that are excluded from MIPS. This expected growth is due in part to reopening of CPC+ and Next Generation ACO for 2018, and the ACO Track 1+ which is projected to have a large number of participants, with a large majority reaching QP status. We estimate that there will be between 180,000 and 245,000 eligible clinicians that will become QPs for the 2018 performance period compared to 110,159 eligible clinicians that are estimated to become QPs during the 2017 performance period, an increase of between 69,841 and 134,841. This expected growth is due in part to reopening of CPC+ and Next Generation ACO for 2018, and the ACO Track 1+ in response to public comments. These models are projected to have a large number of participants, the majority of whom are expected to reach QP status. Additional enrollees in currently active and new Advanced APMs are both considered in the growth estimate.

Our estimates assume clinicians who participated in the 2015 PQRS and who are not QPs in Advanced APMs in the 2017 Quality Payment Program performance period will continue to submit quality data as either MIPS eligible clinicians or voluntary reporters in the 2018 Quality Payment Program performance period. Our participation estimates are reflected in Table 65 for the quality performance category, Table 76 for the advancing information performance category, and Table 78 for the improvement activities performance category. We estimate that 36 percent of the 975,723 ineligible or excluded clinicians are expected to report voluntarily because they reported under PQRS. We expect them to continue to submit because (a) the collection and submission of quality data has been integrated into their clinician practice; and (b) the clinician types that were ineligible from MIPS in years 1 and 2 may potentially become eligible in the future.

We also assume that previous PQRS participants who are not QPs will also submit under the improvement activities performance category, and will submit under the advancing care information performance category unless they receive a significant hardship or other type of exception, including a new significant hardship exception for small practices or are automatically assigned a weighting of zero percent for the advancing care information performance category. We are excluding the 110,159 QPs identified using a preliminary version of the file used for predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. Because we do not have an estimated participation status by TIN/NPI for clinicians who join Advanced APMs in 2017 and 2018, we cannot model the exclusion of the additional estimated 69,841 to 134,841 QPs clinicians that

will become QPs for the 2018 performance period. Hence, these burden estimates may overstate the total burden for data submission under the quality, advancing care information, and improvement activities performance categories.

Our burden estimates assume that 36 percent of clinicians who do not exceed the low- volume threshold or are not eligible clinician types will voluntarily submit quality data under MIPS because they submitted quality data under the PQRS. Hence, the proposed changes in low-volume threshold will increase our estimate of the proportion of clinicians who will submit data voluntarily, but will not affect the estimated number of respondents. Section II.C.2.c. of this rule proposes a low-volume threshold of less than or equal to $90,000 in allowed Medicare Part B charges or less than or equal to 200 Medicare patients. The CY 2017 Quality Payment Program final rule established a low-volume threshold of less than or equal to $30,000 in allowed Medicare Part B charges or less than or equal to 100 Medicare patients.

The revised MIPS requirements and burden estimates for all ICRs listed below (except for CAHPS for MIPS and virtual groups election) were submitted as a request for revision of OMB control number 0938–1314. The CAHPS for MIPS ICR was submitted as a request for revision of OMB control number 0938–1222. The virtual groups ICR has a 60 data day **Federal Register** notice (82 FR 27257) published on June 14, 2017. ICR-comments related to virtual group election are due on or before August 14, 2017.

A. Wage Estimates

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 58 in this proposed rule presents the mean hourly wage (calculated at 100 percent of salary), the cost of fringe benefits and overhead, and the adjusted hourly wage.

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, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. We have selected the occupations in Table 58 based on a study (Casalino et al., 2016) that collected data on the staff in physician's offices involved in the quality data submission process.[27]

In addition, to calculate time costs for beneficiaries who elect to complete the CAHPS for MIPS survey, we have used wage estimates for Civilian, All Occupations, using the same BLS data discussed in this section of the proposed rule. We have not adjusted these costs for fringe benefits and overhead because direct wage costs represent the ''opportunity cost'' to beneficiaries themselves for time spent completing the survey. To calculate time costs for virtual groups to prepare their written formal agreements, we have used wage estimates for Legal Support Workers, All Others.

TABLE 58—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Billing and Posting Clerks	43–3021	$18.06	$18.06	$36.12
Computer Systems Analysts	15–1121	44.05	44.05	88.10
Physicians	29–1060	101.04	101.04	202.08
Practice Administrator (Medical and Health Services Managers)	11–9111	52.58	52.58	105.16
Licensed Practical Nurse (LPN)	29–2061	21.56	21.56	43.12
Legal Support Workers, All Other	23–2099	31.81	31.81	63.62
Civilian, All Occupations	Not applicable	23.86	N/A	23.86

Source: Occupational Employment and Wage Estimates May 2016, U.S. Department of Labor, Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_nat.htm*.

B. Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 59 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians varies across the types of data, and whether the clinician is a MIPS eligible clinician, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 59, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups to the quality, advancing care information, and improvement activities performance categories. For MIPS APMs, the organizations submitting data on behalf of participating MIPS eligible clinicians will vary across categories of data, and in some instances across APMs. For the 2018 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and Other MIPS APMs on behalf of their participant eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the advancing care information performance category, billing TINs will submit data on behalf of participants who are MIPS eligible clinicians. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants because we will assign the improvement activities performance category score at the MIPS APM level and all APM Entity groups in the same MIPS APM will receive the same score. Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in section II.D.5. of this proposed rule.

[27] Lawrence P. Casalino et al., ''US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures,'' Health Affairs, 35, no. 3 (2016): 401–406.

TABLE 59—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN

Category of clinician	Type of data submitted			
	Quality performance category	Advancing care information performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinician
MIPS Eligible Clinicians (not in MIPS APMs) and other clinicians voluntarily submitting data.	As group, virtual groups, or individual clinicians.	As group, virtual groups, or individuals. Clinicians who practice primarily in a hospital, ambulatory surgical center based clinicians, non-patient facing clinicians, PAs, NPs, CNSs and CRNAs are automatically eligible for a zero percent weighting for the advancing care information performance category. Clinicians approved for significant hardship exceptions are also eligible for a zero percent weighting.	As group, virtual groups, or individual clinicians.	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
Facility-based clinicians and groups that elect facility-based measurement.	Clinicians and groups electing facility-based measurement will receive a quality score based on their facility's Hospital VBP data submission. The burden has been previously counted under the Hospital VBP rule, and is not included in burden estimates here.	Facility-based clinicians may be eligible for a zero percent weighting for the advancing care information category.	As groups, virtual groups, or individual clinicians.	Facility-based clinicians that elect facility-based measurement make the election online.
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs).	ACOs submit to the CMS Web Interface on behalf of their participating MIPS eligible clinicians. [Not included in burden estimate because quality data submission to fulfill requirements of the Shared Savings Program and Next Generation ACO models are not subject to the Paperwork Reduction Act.][28]	Each group TIN in the APM Entity reports advancing care information to MIPS.[29]	CMS will assign the same improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program.[30] [The burden estimates assume no improvement activity reporting burden for APM participants.]	Advanced APM Entities will make election for participating MIPS eligible clinicians.
Eligible Clinicians participating in Other MIPS APMs.	MIPS APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians [Not included in burden estimate because quality data submission to fulfill requirements of Innovation Center models are not subject to the Paperwork Reduction Act.].	Each MIPS eligible clinician in the APM Entity reports advancing care information to MIPS through either group TIN or individual reporting. [The burden estimates assume group TIN-level reporting.]	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates assume no improvement activities performance category reporting burden for APM participants.]	Advanced APM Entities will make election for participating eligible clinicians.

[28] Sections and 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the Paperwork Reduction Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a(d)(3), respectively).

[29] For MIPS APMs other than the Shared Savings Program, both group TIN and individual clinician advancing care information data will be accepted. If both group TIN and individual scores are submitted for the same MIPS APM Entity, CMS would take the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for the APM Entity score.

[30] APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores is below the maximum improvement activities score.

The policies finalized in the CY 2017 Quality Payment Program final rule and proposed in this rule create some additional data collection requirements

not listed in Table 59. These additional data collections, some of which were previously approved by OMB under control numbers 0938–1314 and 0938–1222 are as follows:

- Self-nomination of new and returning QCDRs and registries (0938–1314).
- CAHPS for MIPS survey completion by beneficiaries (0938–1222).
- Approval process for new and returning CAHPS for MIPS survey vendors.
- Call for new improvement activities.
- Other Payer Advanced APM identification: other payer initiated process.
- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS.

C. ICR Regarding Burden for Virtual Group Election (§ 414.1315)

As described in section II.C.4.b. of this proposed rule, virtual groups are defined by a combination of two or more TINs and must report as a virtual group on measures in all quality, improvement activities, and advancing care information performance categories as virtual groups. Virtual groups may submit data through any of the mechanisms available to groups. We refer to section II.C.4. on additional requirements for virtual groups.

We propose an optional 2-stage process for enrollment. In stage 1, MIPS eligible clinicians have the option to request a determination of their eligibility to form a virtual group before they form a group and begin the stage 2 submission of an election to participate in a virtual group. For clinicians or groups that do not choose to participate in stage 1 of the election process, we will make an eligibility determination during stage 2 of the election process. We refer readers to section II.C.4.e. of this proposed rule for a discussion of the proposed virtual group election process.

As proposed in II.C.4.e. of this proposed rule, the submission of a virtual group election must include, at a minimum, detailed information pertaining to each TIN and NPI associated with the virtual group and detailed information for the virtual group representative, as well as confirmation of a written formal agreement between members of the virtual group.

We assume that virtual group participation will be relatively low in the first year because we have heard from stakeholders that they need at least 3–6 months to form groups and establish agreements before signing up. We are not able to give them that much time in the first year, rather closer to 60 days. Because of this we expect the number of virtual groups will be very small in the first year of virtual group implementation. Our assumptions for participation in a virtual group are shown in Table 60. We assume that only those eligible clinicians that reported historically will participate in virtual groups in the first year because of the limited lead time to create processes. Also, while virtual groups may use the same submission mechanisms as groups, we are estimating based on stakeholder feedback that the 16 virtual groups reflected in Table 60 will report by registry. Table 60 also shows that we estimate that approximately 765 MIPS eligible clinicians will decide to join 16 virtual groups for the 2018 MIPS performance period. The virtual groups could range in size from a few clinicians to hundreds of clinicians, as long as each participant is a solo practice or TIN with 10 or fewer eligible clinicians. In order to estimate the number of clinicians available to participate in virtual groups, we used the data prepared to support the 2017 performance period initial determination of clinician eligibility (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015–August 31, 2016. We also used the initial small practice determinations made on the same date range. We estimated the number of clinicians who would not participate due to being a QP using a version of the file used for the predictive qualifying Alternative Payment Model participants (QP) analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. We assume an average of 5 TINs per virtual group with an average of 9.5 clinicians in each TINs across each virtual group or approximately 48 eligible clinicians per virtual group (5 TINs × 9.5 clinicians per TIN). For purposes of this burden estimate for the 2018 MIPS performance period, we assumed that approximately one percent of eligible clinicians will participate in approximately 16 virtual groups consisting of approximately 5 TINs per virtual group will be formed (765 MIPS eligible clinicians ÷ 48 eligible clinicians per virtual group) or 80 TINs total that will participate in virtual groups (16 virtual groups × 5 MIPS eligible clinicians per TIN).

We assume that the virtual election process will require 10 hours per virtual group, similar to the burden of the QCDR or registry self-nomination process finalized in § 414.1400. We assume that 8 hours of the 10 burden hours per virtual group will be computer systems analyst's time or the equivalent with an average labor cost of $88.10/hour, and an estimated cost of $704.80 per virtual group ($88.10/hour × 8 hours). We also assume that 2 hours of the 10 burden hours per virtual group will be legal support services professionals assisting in formulating the written virtual agreement with an average labor cost of $63.62/hour, with a cost of $127.24 per virtual group ($63.62/hour × 2 hours). Therefore, the total burden cost per virtual group associated with the election process is $832.04 ($704.80 + $127.24). We also assume that 16 new virtual groups will go through the election process leading to a total burden of $13,313 ($832.04 × 16 virtual groups). We estimate that the total annual burden hours will be 160 (16 virtual groups × 10 hours).

TABLE 60—ESTIMATED BURDEN FOR VIRTUAL GROUP ELECTION PROCESS

	Burden estimate
Total Estimated Number of MIPS eligible clinicians in TINs of 10 eligible clinicians or fewer submitting data in MIPS (a)	765
Total Estimated Number of eligible TINs (10 eligible clinicians or fewer) (b)	80
Estimated Number of Virtual Groups (c)	16
Estimated Total Annual Burden Hours for Virtual Group to prepare written formal agreement (d)	2
Estimated Total Annual Burden Hours for Virtual Group Representative to Submit Application to Form Virtual Group (e)	8
Estimated Total Annual Burden Hours per Virtual Group (f)	10
Estimated Total Annual Burden Hours for Virtual Groups (g) = (c) * (f)	160
Estimate Cost to Prepare Formal Written Agreement (@legal support services professional's labor rate of $63.62) (h)	$127.24
Estimated Cost to Elect Per Virtual Group (@computer systems analyst's labor rate of $88.10/hr.) (i)	$704.80
Estimated Total Annual Burden Cost Per Virtual Group (j)	$832.04

TABLE 60—ESTIMATED BURDEN FOR VIRTUAL GROUP ELECTION PROCESS—Continued

	Burden estimate
Estimated Total Annual Burden Cost (k) = (c) * (j)	$13,313

While the formation of virtual groups will result in a burden for virtual group registration, we also estimate that the formation of virtual groups will result in a decline in burden from other forms of data submission. Because we assume burden is the same for each organization (group, virtual group, or eligible clinician) submitting quality, improvement activities or advancing care information performance category data, virtual groups will reduce burden by reducing the time needed to prepare data for submission, review measure specifications, register or elect to submit data via a mechanism such as QCDR, registry, CMS Web Interface, or EHR. This reduction in burden is described in each of the quality, improvement activities, and advancing care information performance category sections below.

As stated earlier, the information collection request for the virtual group election process will be submitted for OMB review and approval separately from this rulemaking process. Please note that the 60-day **Federal Register** notice already published on June 14, 2017 (82 FR 27257) and the related comment period ends August 14, 2017. When the 30-day **Federal Register** notice publishes, it will not only announce that we are formally submitting the information collection request to OMB but it will also inform the public on its additional opportunity to review the information collection request and submit comments.

D. ICR Regarding Burden for Election of Facility-Based Measurement (§ 414.1345)

In section II.C.7.a.(4) of this proposed rule, we propose that for the 2020 MIPS payment year (2018 MIPS performance period), we would allow facility-based MIPS eligible clinicians to be given a MIPS score in the quality and cost performance categories that is based on the performance of the facility in which they provide services. We propose at § 414.1380(e)(2)(i) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they furnish 75 percent or more of their covered professional services (as defined in section 1848(k)(3)(A) of the Act) in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, as identified by place of service code 21, and the emergency room, as identified by place of service code 23, based on claims for a period prior to the performance period as specified by CMS.

These MIPS eligible clinicians may elect to participate in facility-based measurement during the performance period. For the 2020 MIPS payment year (2018 MIPS performance period), we will base our assumptions for these eligible clinicians on the Hospital VBP Program.

In Table 61, we estimate participation in facility-based measurement, based on 2015 data from the PQRS and the first 2019 payment year MIPS eligibility and special status file as described in 81 FR 77069 and 77070.[31] We estimate 18,207 respondents (17,943 MIPS eligible clinicians who practice primarily in the hospital electing as individuals and 264 groups with 75 percent or more of their clinicians qualifying as clinicians who practice primarily in the hospital) will elect facility-based measurement in the 2018 MIPS performance period. We estimate that the 17,943 individual clinicians electing facility-based scoring are comprised of 20 percent (10,353) of a total of the approximately 51,767 of clinicians who practice primarily in the hospital that previously submitted as individuals in the 2017 MIPS performance period; 80 percent (7,590) of a total of 9,488 clinicians who practice primarily in the hospital that we estimate will not have submitted in the 2017 MIPS performance period. We believe that the 80 percent (7,590) of the total 9,488 would not have submitted in the 2017 MIPS performance period because of the additional effort required to report MIPS measures in addition to measures required for the Hospital Value-Based Purchasing program. We have heard this from hospitalists and other clinicians and we believe that the inclusion of this opportunity within MACRA was in response to this concern. We estimate that 20 percent (or 264) of groups that would have previously submitted on behalf of clinicians in the 2017 MIPS performance period will elect facility-based measurement on behalf of their 12,125 clinicians.

TABLE 61—ESTIMATED NUMBER OF INDIVIDUAL CLINICIANS AND GROUPS WHO PRACTICE PRIMARILY IN THE HOSPITAL TO ELECT FACILITY-BASED MEASUREMENT

	Counts
Estimated number of clinicians who practice primarily in the hospital that previously submitted as individuals under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (a)	10,353
Estimated number of clinicians who practice primarily in the hospital that did not submit under the 2017 MIPS performance period to elect facility-based measurement as individuals in the 2018 MIPS performance period (b)	7,590
Estimated number of clinicians who practice primarily in the hospital to elect facility-based measurement as individuals in the 2017 MIPS performance period (c) = (a) + (b)	17,943
Estimated number of clinicians who practice primarily in the hospital that previously submitted as groups under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (d)	12,125
Estimated number of groups who practice primarily in the hospital that previously submitted on behalf of clinicians as groups under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (e)	264
Estimated number of respondents that elect facility-based measurements (including individual clinicians who practice primarily in the hospital electing facility-based measurement and groups electing facility-based measurement) (f) = (c) + (e)	18,207

[31] The data used for our estimates defined hospital-based clinicians as those who furnish 75 percent or more of their covered professional service in sites of service identified by place service codes 21, 22, or 23. The proposal defines facility-based clinicians as those who furnish 75 percent or more of their covered professional service in sites of service identified by place service codes 21 and 23.

Although the election of facility-based measurement generates burden, it will also result in the reduction of burden in the quality performance category because certain clinicians and groups will no longer be required to submit data for this category. Hence, our burden estimates for the quality performance category consider the reduction in burden for clinicians who practice primarily in the hospital that previously submitted data for this performance category and elected to use facility-based measurement. The reduction in burden is described in the quality performance category section below. We assume that there will be no reduction in burden related to the advancing care information performance category because MIPS eligible clinicians who practice primarily in the hospital are not required to submit data for this performance category.

As shown in Table 62, we estimate that the election to participate via facility-based measurement will take 1 hour of staff time, comparable to the CMS Web Interface registration process. We assume that the staff involved in the election process to participate via facility-based measurement will mainly be billing clerks or their equivalent, who have an average labor cost of $36.12/hour. Therefore, assuming the total burden hours per group or individual clinician associated with the election process is 1 hour, the total annual burden hours are 18,207 (18,207 groups or individual clinicians × 1 hour). We estimate that the total cost to groups and individual clinicians associated with the election process will be approximately $36.12 ($36.12 per hour × 1 hour per group or eligible clinician). We also assume that 18,207 individual clinicians or groups will go through the election process leading to a total burden of $657,637 ($36.12 × 18,207 clinicians).

TABLE 62—ESTIMATED BURDEN FOR ELECTION TO PARTICIPATE IN FACILITY-BASED MEASUREMENT

	Burden estimate
Estimated number of respondents to elect facility-based measurements (including individual clinicians who practice primarily in the hospital electing facility-based measurement and groups electing facility-based measurement) (a)	18,207
Estimated number of Burden Hours Per Group or Eligible Clinician to Elect Facility-based Measurement (b)	1
Estimated Total Annual Burden Hours (c) = (a) * (b)	18,207
Estimated Cost Per Clinician or Group Practice to Elect Facility-Based Measurement (@billing clerk's labor rate of $36.12/hr.) (d)	$36.12
Estimated Total Annual Burden Cost (e) = (c) * (d)	$657,637

E. ICRs Regarding Burden for Third Party Reporting (§ 414.1400)

Under MIPS, quality, advancing care information, and improvement activities performance category data may be submitted via relevant third party intermediaries, such as qualified registries, QCDRs and health IT vendors. The CAHPS for MIPS survey data, which counts as one quality performance category measure, can be submitted via CMS-approved survey vendors. The burdens associated with qualified registry and QCDR self-nomination and the CAHPS for MIPS survey vendor applications are discussed below.

1. Burden for Qualified Registry and QCDR Self-Nomination [32]

For the 2017 MIPS performance period, 120 qualified registries and 113 QCDRs were qualified to report quality measures data for purposes of the PQRS, an increase from 114 qualified registries and 69 QCDRs in CY 2016.[33] Under MIPS, we believe that the number of QCDRs and qualified registries will continue to increase because: (1) Many MIPS eligible clinicians will be able to use the qualified registry and QCDR for all MIPS submission (not just for quality submission) and (2) QCDRs will be able to provide innovative measures that address practice needs. Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to us on their participants' behalf will need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups, unless the qualified registry or QCDR was qualified to submit on behalf of MIPS eligible clinicians or groups for prior program years and did so successfully.

We estimate that the self-nomination process for qualifying additional qualified registries or QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 1 hour per qualified registry or QCDR to complete the online self-nomination process. The self-nomination form is submitted electronically using a web-based tool. We are proposing to eliminate the option of submitting the self-nomination form via email that was available in the transition year.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as meeting with CMS officials when additional information is needed. In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capability (for non-MIPS quality measures) that compares the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For non-MIPS measures the QCDR must provide to us, if available, data from years prior (for example, 2016 data for the 2018 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their Web site prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a qualified registry or QCDR will spend an additional 9 hours performing various other functions related to being a MIPS qualified registry or QCDR.

As shown in Table 63, we estimate that the staff involved in the qualified registry or QCDR self-nomination process will mainly be computer systems analysts or their equivalent, who have an average labor cost of

[32] We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS.

[33] The full list of qualified registries for 2017 is available at *https://qpp.cms.gov/docs/QPP_MIPS_2017_Qualified_Registries.pdf* and the full list of QCDRs is available at *https://qpp.cms.gov/docs/QPP_2017_CMS_Approved_QCDRs.pdf*.

$88.10/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, the annual burden hours is 2,330 (233 (113 + 120) QCDRs or qualified registries × 10 hours). We estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $881.00 ($88.10 per hour × 10 hours per qualified registry). We also estimate that 233 qualified registries or QCDRs will go through the self-nomination process leading to a total burden of $205,273 ($881.00 × 233).

The burden associated with the qualified registry and QCDR submission requirements in MIPS will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry or QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the advancing care information performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry or QCDR and the number of applicable measures. However, we believe that qualified registries and QCDRs already perform many of these activities for their participants. We believe the estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of total annual burden hours and total annual cost burden associated with a qualified registry or QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 63—ESTIMATED BURDEN FOR QCDR AND REGISTRY SELF-NOMINATION

	Burden estimate
Estimated number of Qualified registries or QCDRs Self-Nominating (a)	233
Estimated Total Annual Burden Hours Per Qualified Registry or QCDR (b)	10
Estimated Total Annual Burden Hours for Qualified Registries or QCDRs (c) = (a) * (b)	2,330
Estimated Cost Per Qualified Registry or QCDR (@computer systems analyst's labor rate of $88.10/hr.) (d)	$881.00
Estimated Total Annual Burden Cost for Qualified registries or QCDRs (e) = (a) * (d)	$205,273

2. Burden for CAHPS for MIPS Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the definition, criteria, required forms, and vendor business requirements needed to participate in MIPS as a survey vendor. For purposes of MIPS, we defined a CMS-approved survey vendor at § 414.1305 as a survey vendor that is approved by us for a particular performance period to administer the CAHPS for MIPS survey and transmit survey measures data to us. At § 414.1400(i), we require that vendors undergo the CMS-approval process each year in which the survey vendor seeks to transmit survey measures data to us. We finalized the criteria for a CMS-approved survey vendor for the CAHPS for MIPS survey.

We estimate that it will take a survey vendor 10 hours to submit the information required for the CMS-approval process, including the completion of the Vendor Participation Form and compiling documentation, including the quality assurance plan,that demonstrates that they comply with Minimum Survey Vendor Business Requirements. This is comparable to the burden of the QCDR and qualified registry self-nomination process. As shown in Table 64, we assume that the survey vendor staff involved in collecting and submitting the information required for the CAHPS for MIPS certification will be computer systems analysts, who have an average labor cost of $88.10/hour. Therefore, assuming the total burden hours per CAHPS associated with the application process is 10 hours, the annual burden hours is 150 (15 CAHPS vendors × 10 hours). We estimate that the total cost to each CAHPS vendor associated with the application process will be approximately $881.00 ($88.10 per hour × 10 hours per CAHPS vendor). We estimate that 15 CAHPS vendors will go through the process leading to a total burden of $13,215 ($881.00 × 15 CAHPS vendors).

Based on the assumptions previously discussed, we provide an estimated number of total annual burden hours and total annual cost burden associated with the survey vendor approval process in Table 64.

TABLE 64—ESTIMATED BURDEN FOR CAHPS SURVEY VENDOR APPLICATION

	Burden estimate
Estimated number of New CAHPS Vendors Applying (a)	15
Estimated number of Burden Hours Per Vendor to Apply (b)	10
Estimated Cost Per Vendor Reporting (@computer systems analyst's labor rate of $88.10/hr.) (c)	$881.00
Estimated Total Annual Burden Hours (d) = (a) * (b)	150
Estimated Total Annual Burden Cost for CAHPS Vendor Application Process (e) = (a) * (c)	$13,215

F. ICRs Regarding the Quality Performance Category (§ 414.1330 and § 414.1335)

Two groups of clinicians will submit quality data under MIPS: those who submit as MIPS eligible clinicians, and other clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments.

Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2015 was 69 percent. For purposes of these analyses, we assume that clinicians who

participated in the 2015 PQRS and who are not QPs in Advanced APMs in the 2017 Quality Payment Program performance period will continue to submit quality data as either MIPS eligible clinicians or voluntary reporters in the 2018 MIPS performance period. In addition, as shown in Table 62, regarding our burden estimates for election of facility-based measurement, we assume that approximately 18,207 individual clinicians or groups will elect to participate in facility-based measurement for the 2018 MIPS performance period and will not be required to submit any additional quality performance category data under MIPS. Based on 2015 data from the PQRS, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015—August 31, 2016, and a version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. We estimate that at least 92 percent of MIPS eligible clinicians not participating in MIPS APMs will submit quality performance category data including those participating as individual clinicians, groups, or virtual groups. We assume that 100 percent of MIPS APM Entities will submit quality data to CMS as required under their models.[34] We anticipate that the professionals submitting data voluntarily will include clinicians that are ineligible for the Quality Payment Program, clinicians that do not exceed the low-volume threshold, and newly enrolled Medicare clinicians. Based on those assumptions, using data from the 2015 PQRS, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*), and a preliminary version of the file used for the predictive QP analysis made available on *qpp.cms.gov* on June 2, 2017, we estimate that an additional 292,351 clinicians, or 36 percent of clinicians excluded from or ineligible from MIPS, will submit MIPS quality data voluntarily. Because in the projected growth in the number of QPs over time, we are predicting a decline in the rate of voluntary quality data submission among clinicians excluded from or ineligible for MIPS relative to our estimated voluntary reporting rate of 45 percent in the CY 2017 Quality Payment Program final rule. Historically, clinicians who are expected to be QPs in 2018 MIPS performance period were much more likely to have submitted quality data under the 2015 PQRS than other clinicians excluded from or ineligible from MIPS. Due to data limitations, our assumptions about quality performance category participation for the purposes of our burden estimates differs from our assumptions about quality performance category participation in the impact analysis.[35]

Our burden estimates for data submission combine the burden for MIPS eligible clinicians and other clinicians submitting data voluntarily. Apart from clinicians who practice primarily in the hospital electing facility-based measurement and clinicians that became QPs in the first QP performance period, we assume that clinicians will continue to submit quality data under the same submission mechanisms that they used under the 2015 PQRS. As discussed in more detail in the section of this proposed rule describing the burden for facility-based measurement (III.D.), we assume that some eligible clinicians who practice primarily in the hospital will elect facility-based measurement, rather than submit quality data via other mechanisms. Further, as discussed in more detail in the section of this proposed rule describing the burden for the virtual group application process (III.C.), we assume that the approximately 80 TINs that elect to form the approximately 16 virtual groups will continue to use the same submission mechanism as under the 2015 PQRS, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that MIPS APM Entities submit to fulfill the requirements of their models. Sections 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the Paperwork Reduction Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a(d)(3), respectively).[36] Tables 65, 66, and 67 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians via each of the quality submission mechanisms. The proposed policies related to both virtual groups and facility-based measurement are reflected, as is the proposed policy to score quality measures submitted via multiple submission mechanisms.

Table 65 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians, groups, or virtual groups in the 2018 MIPS performance period. The first step was to estimate the number of clinicians to submit as an individual clinician or group via each mechanism during the 2017 MIPS performance period using 2015 PQRS data on individuals and groups submitting through various mechanisms and excluding clinicians identified as QPs in a preliminary version of the file used for the predictive qualifying APM participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. The second step was to subtract out the estimated number of clinicians who practice primarily in the hospital to elect facility-based scoring as groups or individuals in the 2018 MIPS performance period. Further detail on our methods to estimate the number of clinicians who practice primarily in the hospital to elect facility-based scoring as individual clinicians or groups is provided on the burden for the election of facility-based measurement (section III.D. of this proposed rule).

Based on these methods, Table 65 shows that in the 2018 MIPS performance period, an estimated 364,002 clinicians will submit as individuals via claims submission mechanisms; 225,569 clinicians will submit as individuals, or as part of groups or virtual groups via qualified registry or QCDR submission mechanisms; 115,241 clinicians will submit as individuals, or as part of groups or virtual groups via EHR submission mechanisms; and 101,939 clinicians will submit as part of groups via the CMS Web Interface.

Our estimated numbers of clinicians to submit as individual clinicians,

[34] We estimate that 110,159 clinicians that participated in the 2015 PQRS will be QPs who will not be not required to submit MIPS quality performance category data under MIPS, and are not included in the numerator or denominator of our participation rate.

[35] As noted, the COI section of this rule uses the actual overall average participation rate of 92 percent in quality data submission based on 2015 PQRS data. The RIA section of this rule uses the actual participation rate for practices with more than 15 clinicians and assumes a minimum 90 percent participation (standard assumption or 80 percent participation (alternative assumption) for practices with 1–15 clinicians.

[36] Our estimates do reflect the burden that MIPS APM participants of submitting advancing care information data, which is outside the requirements of their models.

groups, or virtual groups via each submission mechanism account for the policy proposed under section II.C.6.a.(1) of this rule that individual clinicians, groups, and virtual groups can be scored on data submitted via multiple submission mechanisms. Hence, the estimated numbers of individual clinicians, groups, and virtual groups to submit via the various submission mechanisms are not mutually exclusive, and reflect the occurrence of individual clinicians or groups that submitted data via multiple mechanism under the 2015 PQRS.

TABLE 65—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY MECHANISM

	Claims	QCDR/registry	EHR	CMS web interface
Estimated number of clinicians to submit via mechanism (as individual clinicians, groups, or virtual groups) in Quality Payment Program Year 1 (excludes QPs) (a)	371,987	236,908	118,395	101,939
Subtract out: Estimated number of clinicians to submit via mechanism (as individual clinicians, groups or virtual groups) in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	7,985	11,339	3,154	0
Estimated number of clinicians to submit via mechanism (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs and facility-based measurement) (c) = (a) − (b)	364,002	225,569	115,241	101,939

Table 65 provides estimates of the number of clinicians to submit quality measures via each mechanism, regardless of whether they decide to submit as individual clinicians or as part of groups or virtual groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group or virtual group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups or virtual groups.

Table 66 uses methods similar to those described for Table 65 to estimate the number of clinicians to submit as individual clinicians via each mechanism in Quality Payment Program Year 2. We estimate that approximately 364,002 clinicians will submit as individuals via claims submission mechanisms; approximately 86,046 clinicians will submit as individuals via qualified registry or QCDR submission mechanisms; and approximately 60,253 clinicians will submit as individuals via EHR submission mechanisms. Individual clinicians cannot elect to submit via CMS Web Interface. Consistent with the proposed policy to allow individual clinicians to be scored on quality measures submitted via multiple mechanisms, our columns in Table 66 are not mutually exclusive.

TABLE 66—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS

	Claims	QCDR/registry	EHR	CMS web interface
Estimated number of Clinicians to submit data as individuals in Quality Payment Program Year 1 (excludes QPs) (a)	371,987	88,078	60,589	0
Subtract out: Estimated number of clinicians to submit via mechanism as individuals in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	7,985	2,032	336	0
Estimated number of clinicians to submit via mechanism as individuals in Quality Payment Program Year 2 (excludes QPs and facility-based measurement) (c) = (a) − (b)	364,002	86,046	60,253	0

Table 67 provides our estimated counts of groups or virtual groups to submit quality data on behalf of clinicians via each mechanism in the 2018 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. Except for groups who practice primarily in the hospital electing facility-based measurement and groups comprised entirely of QPs, we assume that groups that submitted quality data as groups under the 2015 PQRS will continue to submit quality data either as groups or virtual groups via the same submission mechanisms in the 2018 MIPS performance period. The first step in estimating the numbers of groups or virtual groups to submit via each mechanism in the 2018 MIPS performance period was to estimate the number of groups to submit on behalf of clinicians via each mechanism in the 2017 MIPS performance period. We used 2015 PQRS data on groups submitting on behalf of clinicians via various mechanisms and excluded groups comprised entirely of QPs in a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016. The second step was to subtract out the estimated number of groups who practice primarily in the hospital that will elect facility-based measurement. Further detail on our methods to estimate the number of groups who practice primarily in the hospital to elect facility-based scoring on behalf of clinicians is provided in section III.D. of this proposed rule, on the burden for the election of facility-based measurement. The third and fourth steps in Table 67 reflect our assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations to submit quality data on behalf of clinicians. We assume that 40 groups that previously submitted on behalf of clinicians via QCDR or qualified registry submission mechanisms will elect to form 8 virtual groups that will submit via QCDR and qualified registry submission mechanisms. We assume that another 40 groups that previously submitted on

behalf of clinicians via EHR submission mechanisms will elect to form another 8 virtual groups via EHR submission mechanisms. Hence, the third step in Table 67 is to subtract out the estimated number of groups under each submission mechanism that will elect to form virtual groups, and the fourth step in Table 67 is to add in the estimated number of virtual groups that will submit on behalf of clinicians via each submission mechanism.

Specifically, we assumed that 2,455 groups and virtual groups will submit data via QCDR/registry submission mechanisms on behalf of 146,676 clinicians; 817 groups and virtual groups will submit via EHR submission mechanisms on behalf of 56,772 eligible clinicians; and 298 groups will submit data via the CMS Web Interface on behalf of 102,914 clinicians. Groups cannot elect to submit via claims submission mechanism.

TABLE 67—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY MECHANISM ON BEHALF OF CLINICIANS

	Claims	QCDR/registry	EHR	CMS Web interface
Estimated number of groups to submit via mechanism (on behalf of clinicians) in Quality Payment Program Year 1 (excludes QPs) (a)	0	2,672	928	298
Subtract out: Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	0	185	79	0
Subtract out: Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 1 that will submit as Virtual Groups in Quality Payment Program Year 2 (c)	0	40	40	0
Add in: Estimated number of virtual groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (d)	0	8	8	0
Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (e) = (a) − (b) − (c) + (d)	0	2,455	817	298

These burden estimates have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' work flows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality data codes into the office workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice. Further, these burden estimates are based on historical rates of participation in the PQRS program, and the rate of participation in MIPS are expected to differ.

We believe the burden associated with submitting the quality measures will vary depending on the submission method selected by the clinician, group, or virtual group. As such, we break down the burden estimates by clinicians, groups, and virtual groups by the submission method used.

We anticipate that clinicians and groups using QCDR, qualified registry, and EHR submission mechanisms will have the same start-up costs related to reviewing measure specifications. As such, we estimate for clinicians, groups, and virtual groups using any of these three submission mechanisms a total of 7 staff hours needed to review the quality measures list, review the various submission options, select the most appropriate submission option, identify the applicable measures or specialty measure sets for which they can report the necessary information, review the measure specifications for the selected measures or measures group, and incorporate submission of the selected measures or specialty measure sets into the office work flows. Building on data in a recent article, Casalino et al. (2016), we assume that a range of expertise is needed to review quality measures: 2 hours of an office administrator's time, 1 hour of a clinician's time, 1 hour of an LPN/medical assistant's time, 1 hour of a computer systems analyst's time, and 1 hour of a billing clerk's time.[37] In the CY 2017 Quality Payment Program final rule we estimated 3 hours for an administrator's time for data submission. Because the new CMS Application Programming Interface (API) will be available for EHR, registry and QCDR, and CMS Web Interface submission mechanisms, we have reduced our estimate to 2 hours of an office administrator's time for data submission. This CMS API will streamline the process of reviewing measure specifications and submitting measures for third party submission mechanisms. (We have also reduced our burden estimate for CMS Web Interface to reflect the new CMS API in a separate section below.).[38]

For the claims submission mechanism, we estimate that the start-up cost for a MIPS eligible clinician's practice to review measure specifications is $596.80, including 3 hours of a practice administrator's time (3 hours × $105.16=$315.48), 1 hour of a clinician's time (1 hour × $202.08/hour=$202.08), 1 hour of an LPN/medical assistant's time (1 hour × $43.12), and 1 hour of a billing clerk's time (1 hour × $36.12/hour = $36.12). These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate tables.

For the purposes of our burden estimates for the claims, qualified registry and QCDR, and EHR submission mechanisms, we also assume that, on average, each clinician, group, or virtual group will submit 6 quality measures.

Our estimated number of respondents for the claims and EHR submission mechanisms increased relative to the estimates in the CY 2017 Quality Payment Program final rule because our estimates now reflect the proposed policy to allow individual clinicians and groups to be scored on quality measures submitted via multiple mechanisms. Our estimated number of respondents for the QCDRs and

[37] Our burden estimates are based on prorated versions of the estimates for reviewing measure specifications in Lawrence P. Casalino et al., ''US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures,'' Health Affairs, 35, no. 3 (2016): 401–406. The estimates were annualized to 50 weeks per year, and then prorated to reflect that Medicare revenue is 30 percent of all revenue paid by insurers, and then adjusted to reflect that the decrease from 9 required quality measures under PQRS to 6 required measures under MIPS.

[38] CMS: New API Will Automate MACRA Quality Measure Data Sharing. *http://healthitanalytics.com/news/cms-new-api-will-automate-macra-quality-measure-data-sharing.*

qualified registries submission mechanisms has declined relative to the CY 2017 Quality Payment final rule because our estimates now reflect the proposed policies allowing certain eligible clinicians who practice primarily in the hospital to elect facility-based measurement, as well as the proposed policy to allow practices of 10 or fewer eligible clinicians to participate as part of a virtual group. The number of respondents for CMS Web Interface has declined relative to the estimates in the CY 2017 Quality Payment Program final rule because our estimates now exclude the CMS Web Interface data submitted by Shared Savings Program and Pioneer ACOs to fulfill the requirement of their models. As noted in this section of the proposed rule, information collections associated with the Shared Savings Program and the testing, evaluation, and expansion of CMS Innovation Center models are not subject to the Paperwork Reduction Act.

1. Burden for Quality Data Submission by Clinicians: Claims-Based Submission

As noted in Table 65, based on 2015 PQRS data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015–August 31, 2016, and a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we assume that 364,002 individual clinicians will submit quality data via claims. We anticipate the claims submission process for MIPS will be operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197.

The total estimated burden of claims-based submission will vary along with the volume of claims on which the submission is based. Based on our experience with the PQRS, we estimate that the burden for submission of quality data will range from 0.22 hours to 10.8 hours per clinician. The wide range of estimates for the time required for a clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 68, we also estimate that the cost of quality data submission using claims will range from $19.38 (0.22 hours × $88.10) to $951.48 (10.8 hours × $88.10). The total estimated annual cost per clinician ranges from the minimum burden estimate of $704.28 to a maximum burden estimate of $1,636.38. The burden will involve becoming familiar with MIPS data submission requirements. As noted in Table 68, we believe that the start-up cost for a clinician's practice to review measure specifications totals 7 hours, which includes 3 hours of a practice administrator's time (3 hours × $105.16 = $315.48), 1 hour of a clinician's time (1 hour × $202.08/hour = $202.08), 1 hour of an LPN/medical assistant's time (1 hour × $43.12 = $43.12), 1 hour of a computer systems analyst's time (1 hour × $88.10 = $88.10), and 1 hour of a billing clerk's time (1 hour × $36.12/hour = $36.12).

Considering both data submission and start-up costs, the total estimated burden hours per clinician ranges from a minimum of 7.22 hours (0.22 + 3 + 1 + 1 + 1 + 1) to a maximum of 17.8 hours (10.8 + 3 + 1 + 1 + 1 + 1). The total estimated annual cost per clinician ranges from the minimum estimate of $704.28 ($19.38 + $315.48 + $88.10 + $43.12 + $36.12 + $202.08) to a maximum estimate of $1,636.38 ($951.48 + $315.48 + $88.10 + $43.12 + $36.12 + $202.08). Therefore, total annual burden cost is estimated to range from a minimum burden estimate of $256,359,329 (364,002 × $704.28) to a maximum burden estimate of $595,645,593 (364,002 × $1,636.38).

Based on the assumptions discussed in this section of the proposed rule, Table 68 summarizes the range of total annual burden associated with clinicians using the claims submission mechanism.

TABLE 68—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE CLAIMS SUBMISSION MECHANISM

	Minimum burden	Median burden	Maximum burden estimate
Estimated number of Clinicians (a)	364,002	364,002	364,002
Burden Hours Per Clinician to Submit Quality Data (b)	0.22	1.58	10.8
Estimated number of Hours Office Administrator Review Measure Specifications (c)	3	3	3
Estimated number of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
Estimated number of Hours LPN Review Measure Specifications (e)	1	1	1
Estimated number of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
Estimated number of Hours Clinician Review Measure Specifications (g)	1	1	1
Estimated Annual Burden hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.22	8.58	17.8
Estimated Total Annual Burden Hours (i) = (a) * (h)	2,628,094	3,123,137	6,479,236
Estimated Cost to Submit Quality Data (@computer systems analyst's labor rate of $88.10/hr.) (j)	$19.38	$139.20	$951.48
Estimated Cost to Review Measure Specifications (@practice administrator's labor rate of $105.16/hr.) (k)	$315.48	$315.48	$315.48
Estimated Cost to Review Measure Specifications (@computer systems analyst's labor rate of $88.10/hr.) (l)	$88.10	$88.10	88.10
Estimated Cost to Review Measure Specifications (@LPN's labor rate of $43.12/hr.) (m)	$43.12	$43.12	$43.12
Estimated Cost to Review Measure Specifications (@billing clerk's labor rate of $36.12/hr.) (n)	$36.12	$36.12	$36.12
Estimated Cost to Review Measure Specifications (@physician's labor rate of $202.08/hr.) (o)	$202.08	$202.08	$202.08
Estimated Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$704.28	$824.10	$1,636.38

TABLE 68—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE CLAIMS SUBMISSION MECHANISM—Continued

	Minimum burden	Median burden	Maximum burden estimate
Estimated Total Annual Burden Cost (q) = (a) * (p)	$256,359,329	$299,974,048	$595,645,593

2. Burden for Quality Data Submission by Individuals, Groups, and Virtual Groups Using Qualified Registry and QCDR Submissions

As noted in Table 65 and based on 2015 PQRS data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015–August 31, 2016, a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we assume that 225,569 clinicians will submit quality data as individuals, groups, or virtual groups via qualified registry or QCDR submissions. Of these, we expect 86,046 clinicians, as shown in Table 66, to submit as individuals and 2,455 groups, as shown in Table 67, are expected to submit on behalf of the remaining 139,523 clinicians. Given that the number of measures required is the same for clinicians, groups, and virtual groups, we expect the burden to be the same for each respondent submitting data via qualified registry or QCDR, whether the clinician is participating in MIPS as an individual, group or virtual group.

We estimate that burdens associated with QCDR submissions are similar to the burdens associated with qualified registry submissions. Therefore, we discuss the burden for both data submissions together below. For qualified registry and QCDR submissions, we estimate an additional time burden for respondents (individual clinicians, groups, and virtual groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the start-up cost for an individual clinician or group to review measure specifications and submit quality data to total $851.35. For review costs, this total includes 3 hours per respondent to submit quality data (3 hours × $88.10/hour = $264.00), 3 hours of a practice administrator's time (2 hours × $105.16/hour = $210.32), 1 hour of a clinician's time (1 hours × $202.08/hour = $202.08), 1 hour of a computer systems analyst's time (1 hour × $88.10/hour = $88.10), 1 hour of an LPN/medical assistant's time, (1 hour × $43.12/hour = $43.12), and 1 hour of a billing clerk's time (1 hour × $36.12/hour = $36.12). Clinicians, groups, and virtual groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a total burden cost of $7.31, at a computer systems analyst's labor rate (.083 hours × $88.10/hour). Hence, we estimate 9.083 burden hours per respondent, with annual total burden hours of 803,855 (9.083 burden hours × 88,501 respondents). The total estimated annual cost per respondent is estimated to be approximately $851.05. Therefore, total annual burden cost is estimated to be $75,318,776 (88,501 × $851.05). Based on these assumptions, we have estimated the burden for these submissions.

TABLE 69—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP OR VIRTUAL GROUP) USING THE QUALIFIED REGISTRY/QCDR SUBMISSION

	Burden estimate
Number of clinicians submitting as individuals (a)	86,046
Number of groups or virtual groups submitting via QCDR or registry on behalf of individual clinicians (b)	2,455
Number of Respondents (groups and virtual groups plus clinicians submitting as individuals) (c) = (a) + (b)	88,501
Estimated Burden Hours Per Respondent to Report Quality Data (d)	3
Estimated number of Hours Office Administrator Review Measure Specifications (e)	2
Estimated number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Estimated number of Hours LPN Review Measure Specifications (g)	1
Estimated number of Hours Billing Clerk Review Measure Specifications (h)	1
Estimated number of Hours Clinician Review Measure Specifications (i)	1
Estimated number of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf) (j)	0.083
Estimated Annual Burden Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Estimated Total Annual Burden Hours (l) = (c) * (k)	803,855
Estimated Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $88.10/hr.) (m)	$264.00
Estimated Cost to Review Measure Specifications (@practice administrator's labor rate of $105.16/hr.) (n)	$210.32
Estimated Cost Computer System's Analyst Review Measure Specifications (@computer systems analyst's labor rate of $88.10/hr.) (o)	$88.10
Estimated Cost LPN Review Measure Specifications (@LPN's labor rate of $43.12/hr.) (p)	$43.12
Estimated Cost Billing Clerk Review Measure Specifications (@clerk's labor rate of $36.12/hr.) (q)	$36.12
Estimated Cost Clinician Review Measure Specifications (@physician's labor rate of $202.08/hr.) (r)	$202.08
Estimated Burden for Submission Tool Registration etc. (@computer systems analyst's labor rate of $88.1/hr.) (s)	$7.31
Estimated Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$851.05

TABLE 69—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP OR VIRTUAL GROUP) USING THE QUALIFIED REGISTRY/QCDR SUBMISSION—Continued

	Burden estimate
Estimated Total Annual Burden Cost (u) = (c) * (t)	$75,318,776

3. Burden for Quality Data Submission by Clinicians, Groups, and Virtual Groups: EHR Submission

As noted in Tables 65, 66 and 67, based on our analysis of 2015 PQRS data, data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015–August 31, 2016, and a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants QP analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between the date range January 1, 2016 through August 31, 2016, we assume that 115,241 clinicians will submit quality data as individuals or groups via EHR submissions; 60,253 clinicians are expected to submit as individuals; and 817 groups are expected to submit on behalf of 56,772 clinicians. We expect the burden to be the same for each respondent submitting data via qualified registry or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the EHR submission mechanism, the individual clinician or group may either submit the quality measures data directly to us from their EHR or utilize an EHR data submission vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the EHR submission mechanism, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from their EHR, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for submission of quality measures data via EHR is similar for clinicians, groups, and virtual groups who submit their data directly to us from their CEHRT and clinicians, groups, and virtual groups who use an EHR data submission vendor to submit the data on their behalf. To submit data to us directly from their CEHRT, clinicians, groups, and virtual groups must have access to a CMS-specified identity management system which we believe takes less than 1 hour to obtain. Once a clinician or group has an account for this CMS-specified identity management system, they will need to extract the necessary clinical data from their EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

We estimate that obtaining an account on a CMS-specified identity management system will require 1 hour per respondent for a cost of $88.10 (1 hour × $88.10/hour), and that submitting a test data file to us will also require 1 hour per respondent for a cost of $88.10 (1 hour × $88.10/hour). For submitting the actual data file, we believe that this will take clinicians or groups no more than 2 hours per respondent for a cost of submission of $176.20 (2 hours × $88.10/hour). The burden will involve becoming familiar with MIPS submission. We believe that the start-up cost for a clinician or group to submit the test data file and review measure specifications is a total 7 hours, 1 hour for the test data submission and 6 hours for reviewing measuring which includes 2 hours of a practice administrator's time (2 hours × $105.16/hour = $210.32), 1 hour of a clinician's time (1 hour × $202.08/hour = $202.08), 1 hour of a computer systems analyst's time (1 hour × $88.10/hour = $88.10), 1 hour of an LPN/medical assistant's time (1 hour × $43.12/hour = $43.12), and 1 hour of a billing clerk's time (1 hour × $36.12/hour = $36.12). Hence, we estimated 10 total burden hours per respondent with annual total burden hours of 610,700 (10 burden hours × 61,070 respondents). The total estimated annual cost per respondent is estimated to be $932.14. Therefore, total annual burden cost is estimated to be $56,925,790 = (61,070 respondents × $932.14).

Based on the assumptions discussed in this section of the proposed rule, we have estimated the burden for the quality data submission using EHR submission mechanism below.

TABLE 70—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP OR VIRTUAL GROUP) USING THE EHR SUBMISSION MECHANISM

	Burden estimate
Number of clinicians submitting as individuals (a)	60,253
Number of Groups and Virtual Groups submitting via EHR on behalf of individual clinicians (b)	817
Number of Respondents (Groups and Virtual Groups plus clinicians submitting as individuals) (c) = (a) + (b)	61,070
Estimated Burden Hours Per Respondent to Obtain Account in CMS-Specified Identity Management System (d)	1
Estimated Burden Hours Per Respondents to Submit Test Data File to CMS (e)	1
Estimated Burden Hours Per Respondent to Submit MIPS Quality Data File to CMS (f)	2
Estimated number of Hours Office Administrator Review Measure Specifications (g)	2
Estimated number of Hours Computer Systems Analyst Review Measure Specifications (h)	1
Estimated number of Hours LPN Review Measure Specifications (i)	1
Estimated number of Hours Billing Clerk Review Measure Specifications (j)	1
Estimated number of Hours Clinicians Review Measure Specifications (k)	1
Estimated Annual Burden Hours Per Respondent (l) = (d) + (e) + (f) + (g) + (h) + (i) + (j) + (k)	10
Estimated Total Annual Burden Hours (m) = (c) * (l)	610,700

TABLE 70—BURDEN ESTIMATE FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP OR VIRTUAL GROUP) USING THE EHR SUBMISSION MECHANISM—Continued

	Burden estimate
Estimated Cost Per Respondent to Obtain Account in CMS-specified identity management system (@computer systems analyst's labor rate of $88.10/hr.) (n)	$88.10
Estimated Cost Per Respondent to Submit Test Data File to CMS (@computer systems analyst's labor rate of $88.10/hr.) (o)	88.10
Estimated Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $88.10/hr.) (p)	176.20
Estimated Cost to Review Measure Specifications (@practice administrator's labor rate of $105.16/hr.) (q)	210.32
Estimated Cost to Review Measure Specifications (@computer systems analyst's labor rate of $88.10/hr.) (r)	88.10
Estimated Cost to Review Measure Specifications (@LPN's labor rate of $43.12/hr.) (s)	43.12
Estimated Cost to Review Measure Specifications (@clerk's labor rate of $36.12/hr.) (t)	36.12
Estimated Cost to D21Review Measure Specifications (@physician's labor rate of $202.08/hr.) (u)	202.08
Estimated Total Annual Cost Per Respondent (v) = (n) + (o) + (p) + (q) + (r) + (s) + (t) + (u)	932.14
Estimated Total Annual Burden Cost (w) = (c) * (v)	56,925,790

4. Burden for Quality Data Submission via CMS Web Interface

Based on 2015 PQRS data and as shown in Table 67, we assume that 298 groups will submit quality data via the CMS Web Interface in the 2018 MIPS performance period. We anticipate that approximately 252,808 clinicians will be represented.

The burden associated with the group submission requirements under the CMS Web Interface is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Based on experience with PQRS GPRO Web Interface submission mechanism, we estimate that, on average, it will take each group 74 hours of a computer systems analyst's time to submit quality measures data via the CMS Web Interface at a cost of $88.10 per hour, for a total cost of $6,519 (74 hours × $88.10/hour). Our estimate of 74 hours for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and then submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered or uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT. Because the CMS API will streamline the measure submission process for many groups, we have reduced our estimate of the computer system's analyst time needed for submission from 79 hours in the CY 2017 Quality Payment Program final rule to 74 hours. Because each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248), we assume that entering or uploading data for one Medicare beneficiary requires approximately 18 minutes of a computer systems analyst's time (74 hours ÷ 248 patients).

The total annual burden hours are estimated to be 22,052 (298 groups × 74 annual hours), and the total annual burden cost is estimated to be $1,942,662 (298 groups × $6,519).

Based on the assumptions discussed in this section of the proposed rule, we have calculated the following burden estimate for groups submitting to MIPS with the CMS Web Interface.

TABLE 71—BURDEN ESTIMATE FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Estimated number of Eligible Group Practices (a)	298
Estimated Total Annual Burden Hours Per Group to Submit (b)	74
Estimated Total Annual Burden Hours (c) = (a) * (b)	22,052
Estimated Cost Per Group to Report (@computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Cost Per Group (e) = (b) * (d)	$6,519
Estimated Total Annual Burden Cost (f) = (a) * (e)	$1,942,662
	By eligible clinician or group
Estimated number of Participating Eligible Professionals (g)	252,808
Average Burden Hours Per Eligible Professional (h) = (c) ÷ (g)	0.09
Estimated Cost Per Eligible Professional to Report Quality Data (i) = (f) ÷ (g)	$7.68

5. Burden for Beneficiary Responses to CAHPS for MIPS Survey

Under MIPS, groups of two or more clinicians can elect to contract with a CMS-approved survey vendor and use the CAHPS for MIPS survey as one of their six required quality measures. Beneficiaries that choose to respond to the CAHPS for MIPS survey will experience burden.

The usual practice in estimating the burden on public respondents to

surveys such as CAHPS is to assume that respondent time is valued, on average, at civilian wage rates. As previously explained, the BLS data show the average hourly wage for civilians in all occupations to be $23.86. Although most Medicare beneficiaries are retired, we believe that their time value is unlikely to depart significantly from prior earnings expense, and we have used the average hourly wage to compute the dollar cost estimate for these burden hours.

Under the 2018 MIPS performance period, we assume that 461 groups will elect to report on the CAHPS for MIPS survey, which is equal to the number of groups reporting via CAHPS for the PQRS for reporting period 2015.[39] Table 72 shows the estimated annualized burden for beneficiaries to participate in the CAHPS for MIPS Survey. Based on historical information on the numbers of CAHPS for PQRS survey respondents, we assume that an average of 287 beneficiaries will respond per group. Therefore, the CAHPS for MIPS survey will be administered to approximately 132,307 beneficiaries per year (461 groups × an average of 287 beneficiaries per group responding).

We are proposing to use a shorter version of the CAHPS for MIPS survey with 58 items, as compared to 81 items for the version that will be used in the transition year. The proposed shorter survey is estimated to require an average administration time of 12.9 minutes (or 0.22 hours) in English (at a pace of 4.5 items per minute). We assume the Spanish survey would require 15.5 minutes (assuming 20 percent more words in the Spanish translation). Because less than 1 percent of surveys were administered in Spanish for reporting year 2016, our burden estimate reflects the length of the English survey. Our proposal would reduce beneficiary burden compared to the transition year; we estimate that the 81-item survey requires an average administration time of 18 minutes in English and 21.6 minutes in Spanish. Compared to the survey for reporting year 2016, this is a reduction of 5.1 minutes (18 minutes − 12.9 minutes) in administration time for the English version and a reduction of 6.1 (21.6 minutes − 15.5 minutes) minutes in administration time for the Spanish version.

Given that we expect approximately 132,307 respondents per year, the annual total burden hours are estimated to be 29,108 hours (132,307 respondents × 0.22 burden hours per respondent). The estimated total burden annual burden cost is $694,612 (132,307 × $5.25).

TABLE 72—BURDEN ESTIMATE FOR BENEFICIARY PARTICIPATION IN CAHPS FOR MIPS SURVEY

	Burden estimate
Estimated number of Eligible Group Practices Administering CAHPS for Physician Quality Reporting Survey (a)	461
Estimated number of Beneficiaries Per Group Responding to Survey (b)	287
Estimated number of Total Beneficiary Respondents (c) = (a) * (b)	132,307
Estimated number of Burden Hours Per Beneficiary Respondent (d)	0.22
Estimated Cost Per Beneficiary (@labor rate of $23.86/hr.) (e)	$5.25
Estimated Total Annual Burden Hours (f) = (c) * (d)	29,108
Estimated Total Annual Burden Cost for Beneficiaries Responding to CAHPS MIPS (g) = (c) * (e)	$694,612

6. Burden for Group Registration for CMS Web Interface

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 73 we estimate that the registration process for groups under MIPS involves approximately 1 hour of administrative staff time per group. We assume that a billing clerk will be responsible for registering the group and that, therefore, this process has an average computer systems analyst labor cost of $88.10 per hour. Therefore, assuming the total burden hours per group associated with the group registration process is 1 hour, we estimate the total cost to a group associated with the group registration process to be approximately $88.10 ($88.10 per hour × 1 hour per group). We assume that approximately 10 groups will elect to use the CMS Web Interface submission mechanism in the 2018 MIPS performance period. The total annual burden hours are estimated to be 10 (10 groups × 1 annual hour), and the total annual burden cost is estimated to be $881.00 (10 groups × $88.10).

TABLE 73—TOTAL ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Estimated Number of New Groups Registering for CMS Web Interface (a)	10
Estimated Annual Burden Hours Per Group (b)	1
Estimated Total Annual Burden Hours (c) = (a) * (b)	10
Estimated Cost per Group to Register for CMS Web Interface @computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Burden Cost for CMS Web Interface Group Registration (e) = (a) * (d)	$881

[39] Because the CAHPS for PQRS survey was required for groups of 100 or more clinicians under the PQRS, we expect that group participation in CAHPS for MIPS survey, which is optional under MIPS, may be somewhat lower. Hence, we assume that the number of groups electing to use the CAHPS for MIPS survey will be equivalent to the second highest participation rate for CAHPS for PQRS survey, which occurred in year 2015 when 461 groups used the survey. The most popular year of the CAHPS for PQRS survey was reporting year 2016, when 514 groups used the survey.

7. Burden for Group Registration for CAHPS for MIPS Survey

Under MIPS, the CAHPS for MIPS survey counts for one measure towards the MIPS quality performance category and, as a patient experience measure, also fulfills the requirement to submit at least one high priority measure in the absence of an applicable outcome measure. Groups that wish to administer the CAHPS for MIPS survey must register by June of the applicable 12-month performance period, and electronically notify CMS of which vendor they have selected to administer the survey on their behalf. In the 2018 MIPS performance period, we assume that 461 groups will enroll in the MIPS for CAHPS survey.

As shown in Table 74, we assume that the staff involved in the group registration for CAHPS for MIPS Survey will mainly be computer systems analysts or their equivalent, who have an average labor cost of $88.10/hour. We assume the CAHPS for MIPS Survey registration burden estimate includes the time to register for the survey as well as select the CAHPS for MIPS Survey vendor. Therefore, assuming the total burden hours per registration is 1 hour and 0.5 hours to select the CAHPS for MIPS Survey vendor that will be used and electronically notify CMS of their selection, the total burden hours for CAHPS for MIPS registration is 1.5. We estimate the total annual burden hours as 692 (461 groups × 1.5 hours). We estimate the cost per group for CAHPS for MIPS Survey registration is $132.15 ($88.10 × 1.5 hours). We estimate that the total cost associated with the registration process is $60,921 ($132.15 per hour × 461 hours per group).

TABLE 74—BURDEN ESTIMATE FOR GROUP REGISTRATION FOR CAHPS FOR MIPS SURVEY

	Burden estimate
Estimated number of Groups Registering for CAHPS (a)	461
Estimated Total Annual Burden Hours for CAHPS Registration (b)	1.5
Estimated Total Annual Burden Hours for CAHPS Registration (c) = (a) * (b)	692
Estimated Cost to Register for CAHPS@computer systems analyst's labor rate of $88.10/hr.) (d)	$132.15
Estimated Total Annual Burden Cost for CAHPS Registration (e) = (a) * (d)	$60,921

G. ICRs Regarding Burden Estimate for Advancing Care Information Data (§ 414.1375)

During the 2018 MIPS performance period, clinicians, groups, and virtual groups can submit advancing care information data through qualified registry, QCDR, EHR, CMS Web Interface, and attestation data submission methods. We have worked to further align the advancing care information performance category with other MIPS performance categories. We anticipate that most organizations will use the same data submission mechanism for the advancing care information and quality performance categories, and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the advancing care information data submission process. Hence, the burden estimate for the submission of advancing care information data below shows only incremental hours required above and beyond the time already accounted for in the quality data submission process. While this analysis assesses burden by performance category and submission mechanism, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

1. Burden for Advancing Care Information Application

As stated in the CY 2017 Quality Payment Program final rule, some MIPS eligible clinicians may not have sufficient measures applicable and available to them for the advancing care information performance category, and as such, they may apply to have the advancing care information category re-weighted to zero in the following circumstances: insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT (81 FR 77240 through 77243). As described in section II.C.6.f.(7)(a) of this proposed rule, we are proposing to allow MIPS eligible clinicians to apply to have their advancing care information performance category re-weighted to zero through the Quality Payment Program due to a significant hardship exception or exception for decertified EHR technology. We are also proposing that MIPS eligible clinicians who are in small practices (15 or fewer clinicians) may, beginning with the 2018 performance period and 2020 MIPS payment year, request a reweighting to zero for the advancing care information category due to a significant hardship. We are proposing to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as our authority for the significant hardship exceptions.

Table 75 shows the estimated annualized burden for clinicians to apply for a reweighting to zero of their advancing care information performance category due to a significant hardship exception or as a result of a decertification of an EHR, as well as an application for significant hardship by small practices. Based on 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file, we assume 50,689 respondents (eligible clinicians, groups, or virtual groups) will submit a request for reweighting to zero of their advancing care information category due to a significant hardship exception, decertification of an EHR or significant hardship for small practices through the Quality Payment Program. We estimate that 6,699 respondents (eligible clinicians, groups, or virtual groups) will submit a request for a reweighting to zero for the advancing care information performance category due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR, and 43,990 respondents will submit a request for a reweighting to zero for the advancing care information performance category as a small practice. The application to request a reweighting to zero for the advancing care information performance category due to significant hardship is a short online form that requires identifying which type of hardship or if decertification of an EHR applies and a description of how the circumstances impair the ability to submit the advancing care information data, as well

as some proof of circumstances beyond the submitter's control. The estimate to submit this application is 0.5 hours of a computer system analyst's time. Given that we expect 50,689 applications per year, the annual total burden hours are estimated to be 25,345 hours (50,689 respondents × 0.5 burden hours per respondent). The estimated total annual burden is $2,232,850 (50,689 × $44.05).

TABLE 75—BURDEN ESTIMATE FOR APPLICATION FOR ADVANCING CARE INFORMATION REWEIGHTING

	Burden estimate
Number of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship and Other Exceptions (a)	6,699
Number of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship as Small Practice (b)	43,990
Total respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	50,689
Estimated Burden Hours Per Applicant for Advancing Care Information (d)	0.5
Estimated Total Annual Burden Hours (e) = (a) * (c)	25,345
Estimated Cost Per Applicant for Advancing Care Information (@computer systems analyst's labor rate of $88.10/hr.) (f)	$44.05
Estimated Total Annual Burden Cost (g) = (a) * (f)	$2,232,850

2. Number of Organizations Submitting Advancing Care Information Data on Behalf of Eligible Clinicians

A variety of organizations will submit advancing care information data on behalf of clinicians. Clinicians not participating in a MIPS APM can submit as individuals or as part of a group or virtual group. Group TINs may submit advancing care information data on behalf of clinicians in MIPS APMs, or, except for participants in the Shared Savings Program, clinicians in MIPS APMs may submit advancing care information performance category data individually. Because group TINs in APM Entities will be submitting advancing care information data to fulfill the requirements of submitting to MIPS, we have included MIPS APMs in our burden estimate for the advancing care information performance category. Consistent with the list of APMs that are MIPS APMs on the QPP Web site,[40] we assume that 5 MIPS APMs that do not also qualify as Advanced APMs will operate in the 2018 MIPS performance period: Track 1 of the Shared Savings Program, CEC (one-sided risk arrangement), OCM (one-sided risk arrangement), and the Comprehensive Primary Care Plus Model (CPC+). Further, we assume that group TINs will submit advancing care information data on behalf of partial QPs that elect to participate in MIPS.

As shown in Table 76, based on 2015 data from the Medicare EHR Incentive Program and the data prepared to support the 2017 performance period initial determination of clinician eligibility and special status determination (available via the NPI lookup on *qpp.cms.gov*) using a date range of September 1, 2015–August 31, 2016, we estimate that 265,895 individual MIPS eligible clinicians and 301 groups or virtual groups, representing 106,406 MIPS eligible clinicians, will submit advancing care information data. These estimates reflect that under the policies finalized in CY 2017 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of their advancing care information performance category score to zero, including MIPS eligible clinicians that practice primarily in the hospital, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, and non-patient facing clinicians. These estimates also account for the significant hardships finalized in the CY 2017 Quality Payment Program final rule and our proposed policies for significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as exceptions due to decertification of an EHR. Due to data limitations, our estimate of the number of clinicians to submit advancing care information data does not account for our proposal to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, to assign a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ambulatory surgical centers (ASCs).

Further, we anticipate that the 480 Shared Savings Program ACOs will submit data at the ACO participant group TIN-level, for a total of 15,945 group TINs. We anticipate that the three APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, for an estimated total of 100 group TINs submitting data. We anticipate that the 195 APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level, for an estimated total of 6,478 group TINs. Based on a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we estimate 2 APM Entities in the CPC+ model will submit at the group TIN-level, for an estimated total of 2 group TINs submitting data. Based on preliminary data, we assume that 1 CPC+ APM entity will submit data because one or more of its participants is a partial QP, and that 1 CPC+ APM Entity will submit data because some of its participants qualify as either as QPs or partial QPs. The total estimated number of respondents is estimated at 288,721.

[40] *https://qpp.cms.gov/docs/QPP_Advanced_APMs_in_2017.pdf.*

TABLE 76—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT ADVANCING CARE INFORMATION PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Estimated number of respondents	Estimated number of APM entities
Number of Individual clinicians to submit advancing care information (a)	265,895	
Number of groups or virtual groups to submit advancing care information (b)	301	
Shared Savings Program ACO Group TINs (c)	15,945	480
CEC one-sided risk track participants[41] (d)	100	3
OCM one-sided risk arrangement Group TINs (e)	6,478	195
CPC+ TINs (f)	2	2
Total (g) = (a) + (b) + (c) + (d) + (e) + (f)	288,721	680

3. Burden for Submission of Advancing Care Information Data

In Table 76, we estimate that up to approximately 288,721 respondents will be submitting data under the advancing care information performance category, 265,895 clinicians, 301 groups or virtual groups, 15,945 group TINs within the Shared Savings Program ACOs, 100 group TINs within the APM Entity participating in CECs in the one-sided risk track, and 6,478 group TINs within the OCM (one-sided risk arrangement), and 2 CPC+ group TINs. We estimate this is a significant reduction in respondents from the 2017 MIPS performance period as a result of our proposed policy to provide significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as for situations due to decertification of an EHR, and our proposed policy to allow eligible clinicians to participate as part of a virtual group.

In the CY 2017 Quality Payment Program final rule, our burden estimates assumed all clinicians who submitted quality data would also submit under advancing care information. For this proposed rule, MIPS special status eligibility data were available to model exceptions. The majority (214,302) of the difference in our estimated number of respondents is due to the availability of MIPS special status data to identify clinicians and groups that would also not need to report advancing care information data under transition year policies, including hospital-based eligible clinicians, clinician types eligible for automatic reweighting of their advancing care information performance category score, non-patient facing clinicians, and clinicians facing a significant hardship. The remaining decline in respondents is due to policies proposed in this rule, including 25,881 respondents who would be excluded under the new proposed significant hardship exception for small practices.

Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 3 hours of clinician time would be required to collect and submit advancing care information performance category data. We anticipate that the year-over-year consistency of data submission processes, measures, and activities and the further alignment of the advancing care information performance category with other performance categories will reduce the clinician time needed under this performance category in the 2018 MIPS performance period. Further, for some practices the staff mix requirements in the 2018 MIPS performance period may be driven more by transition to 2015 CEHRT. Therefore, as shown in Table 77, the total burden hours for an organization to submit data on the specified Advancing Care Information Objectives and Measures is estimated to be 3 incremental hours of a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data. The total estimated burden hours are 866,163 (288,721 respondents × 3 hours). At a computer systems analyst's hourly rate, the total burden cost is $76,308,960 (288,721 × $264.30/hour).

TABLE 77—ESTIMATED BURDEN FOR ADVANCING CARE INFORMATION PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of respondents submitting advancing care information data on behalf of clinicians (a)	288,721
Estimated Total Annual Burden Hours Per Respondent (b)	3
Estimated Total Annual Burden Hours (c) = (a) * (b)	866,163
Estimated Cost Per Respondent to Submit Advancing Care Information data (@computer systems analyst's labor rate of $88.10/hr.) (d)	$264.30
Estimated Total Annual Burden Cost (e) = (a) * (d)	$76,308,960

H. ICR Regarding Burden for Improvement Activities Submission (§ 414.1355)

Requirements for submitting improvement activities did not exist in the legacy programs replaced by MIPS, and we do not have historical data which is directly relevant. A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group or virtual group through the

[41] The 3 CEC APM Entities reflected in the burden estimate are the non-large dialysis organizations participating in the one-sided risk track.

QCDR and registry, EHR, and CMS Web Interface submission mechanisms will also submit improvement activities data. Further, we assume that clinicians and groups that practice primarily in the hospital that elect facility-based measurement for the quality performance category will also submit improvement activities data. As noted in section II.C.6.g.(3)(c) of the proposed rule, MIPS eligible clinicians participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities score is below the maximum improvement activities score. As represented in Table 78, we estimate 520,654 clinicians will submit improvement activities as individuals during the 2018 MIPS performance period, an estimated 3,818 groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period, and an additional 16 virtual groups to submit improvement activities, resulting in 524,488 total respondents. The burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM level; each APM Entity within the same MIPS APM will be assigned the same score.

TABLE 78—ESTIMATED NUMBERS OF ORGANIZATIONS SUBMITTING IMPROVEMENT ACTIVITIES PERFORMANCE CATEGORY DATA ON BEHALF OF CLINICIANS

	Count
Estimated number of clinicians to participate in Improvement Activities data submission as individuals during the 2018 MIPS performance period (a)	520,654
Estimated number of Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (b)	3,818
Estimated number of Virtual Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (c)	16
Total number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (d) = (a) + (b) + (c)	524,488

In Table 79, we estimate that approximately 524,488 respondents will be submitting data under the improvement activities performance category. Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 2 hours of clinician time would be required to submit data on the specified improvement activities. For this proposed rule, our burden estimate has been revised to assume that the total burden hours to submit data on the specified improvement activities will be 1 hour of computer system analyst time in addition to time spent on other performance categories. Our revised estimate is based on feedback from stakeholders that these are activities they have already been doing and tracking so there is no additional development of material needed. Additionally, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to develop for the 2018 MIPS performance period. The total estimated burden hours are 524,488 (524,488 responses $\times$ 1 hour). At a computer systems analyst's hourly rate, the total burden cost is $46,207,393 (524,488 $\times$ $88.10/hour).

TABLE 79—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (a)	524,488
Estimated Total Annual Burden Hours Per Respondent (b)	1
Estimated Total Annual Burden Hours (c)	524,488
Estimated Cost Per Respondent to Submit Improvement Activities (@computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Burden Cost (e) = (a) * (d)	$46,207,393

I. ICR Regarding Burden for Nomination of Improvement Activities § 414.1360)

For the 2018 MIPS performance period, we are also proposing to allow clinicians, groups, and other relevant stakeholders to nominate new improvement activities using a nomination form provided on the Quality Payment Program Web site at *qpp.cms.gov*, and to send their proposed new improvement activities to us via email. As shown in Table 80, based on response to an informal call for new proposed improvement activities during the transition year, we estimate that approximately 150 organizations (clinicians, groups or other relevant stakeholders) will nominate new improvement activities. We estimate it will take an estimated 0.5 hours per organization to submit an activity to us, including an estimated 0.3 hours per practice for a practice administrator to identify and submit an activity to us via email at a rate of $105.16/hour for a total of $31.55 per activity and clinician review time of 0.2 hours at a rate of $202.08/hour for a total of $40.42 per activity. We estimate that the total annual burden cost is $10,796 (150 $\times$ $71.96).

TABLE 80—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Number of Organizations Nominating New Improvement Activities (a)	150
Estimated Number of Hours Per Practice Administrator to Identify and Propose Activity (b)	0.30
Estimated Number of Hours Per Clinician to Identify Activity (c)	0.20
Estimated Annual Burden Hours Per Respondent (d) = (b) + (c)	0.50
Estimated Total Annual Burden Hours (e) = (a) * (d)	75.00
Estimated Cost to Identify and Submit Activity (@practice administrator's labor rate of $105.16/hr.) (f)	$31.55
Estimated Cost to Identify Improvement Activity (@physician's labor rate of $202.08/hr.) (g)	$40.42
Estimated Total Annual Cost Per Respondent (h) = (f) + (g)	$71.97
Estimated Total Annual Burden Cost (i) = (a) * (h)	$10,796

J. ICRs Regarding Burden for Cost (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not asked to provide any documentation by CD or hardcopy. Therefore, under the cost performance category, we do not anticipate any new or additional submission requirements for MIPS eligible clinicians.

K. ICR Regarding Partial QP Elections (§ 414.1430)

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status before the end of the performance period. For Advanced APMs the burden of partial QP election would be incurred by a representative of the participating APM Entity. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our analyses of a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we assume that approximately 17 APM Entities will face the data submission requirement in the 2018 performance period.

As shown in Table 81, we assume that 17 APM Entities will make the election to participate as a partial QP in MIPS. We estimate it will take the APM Entity representative 15 minutes to make this election. Using a computer systems analyst's hourly labor cost, we estimate a total burden cost of just $375 (17 participant × $22.03).

TABLE 81—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Number of APM Entities Electing Partial QP Status on behalf of their Participants (a)	17
Estimated Burden Hours Per Respondent to Elect to Participate as Partial QP (d)	0.25
Estimated Total Annual Burden Hours (e) = (c) * (d)	4.25
Estimated Cost Per Respondent to Elect to Participate as Partial QP (@computer systems analyst's labor rate of $88.10/hr.) (f)	$22.03
Estimated Total Annual Burden Cost (g) = (c) * (f)	$375

L. ICRs Regarding Other Payer Advanced APM Identification: Payer-Initiated Process (§ 414.1440)

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advanced notice prior to the start of the 2019 QP performance period, and to allow other payers to be involved prospectively in the process, we have outlined in section II.D.6.a. of this proposed rule a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs. This payer-initiated identification process of Other Payer Advanced APMs will begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

As shown in Table 82, we estimate that 300 other payer arrangements will be submitted (50 Medicaid payers, 150 MA Organizations, and 100 Multi-payers) for identification as Other Payer Advanced APMs. The estimated burden to apply is 10 hours per payment arrangement, for a total annual burden hours of 3,000 (300 × 100). We estimate a total cost per payer of $881.00 using a computer system analyst's rate of $88.10/hour (10 × 81.10). The total annual burden cost for all other payers is $264,300 (300 × $881.00).

TABLE 82—BURDEN FOR PROSPECTIVE IDENTIFICATION OF OTHER PAYER ADVANCED APMS

	Burden estimate
Estimated Number of other payer payment arrangements (50 Medicaid, 150 MA Organizations, 100 Multi-payers) (a)	300
Estimated Total Annual Burden Hours Per other payer payment arrangement (b)	10
Estimated Total Annual Burden Hours (c) = (a) * (b)	3,000
Estimated Cost Per Other Payer (@computer systems analyst's labor rate of $88.10/hr.) (d)	$881.00
Estimated Total Annual Burden Cost for Identifying Other Payer Advanced APMs (e) = (a) * (d)	$264,300

M. ICRs Regarding Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare (§ 414.1395)

We estimate 22,400 clinicians and groups who will voluntarily participate in MIPS but will also elect not to participate in public reporting. Table 83 shows that for these voluntary participants, they may submit a request to opt out which is estimated at 0.25 hours of a computer system analyst's labor rate of $88.10. The total annual burden hours for opting out is estimated at 5,600 hours ($22{,}400 \times 0.25$). The total annual burden cost for opting out for all requesters is estimated at $493,472 ($22{,}400 \times \$22.03$).

TABLE 83—BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
Estimated Number of Voluntary Participants Opting Out of Physician Compare (a)	22,400
Estimated Total Annual Burden Hours Per Opt-out Requester (b)	0.25
Estimated Total Annual Burden Hours for Opt-out Requester (c) = (a) * (b)	5,600
Estimated Cost Per Physician Compare Opt-out Request@computer systems analyst's labor rate of $88.10/hr.) (d)	$22.03
Estimated Total Annual Burden Cost for Opt-out Requester (e) = (a) * (d)	$493,472

N. Summary of Annual Burden Estimates

Table 84 includes the total estimated burden of recordkeeping and data submission of the proposed rule 9,391,175 hours with total labor cost of $856,996,819. In order to understand the burden implications of the proposals in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2017 Quality Payment Program final rule into the 2018 performance period. This estimated baseline burden of 9,523,975 hours and a total labor cost of $869,369,094 is lower than the burden approved for information collection related to the CY 2017 Quality Payment Program final rule [42] because we anticipate greater respondent familiarity with the measures and data submission methods in their second year of participation and because the number of QPs that are excluded from MIPS is expected to continue to grow. Further, our estimated baseline burden estimates reflect the recent availability of data sources to more accurately reflect the number of the organizations exempt from the advancing care information performance category.

We estimate that the proposed rule will reduce burden by 132,620 hours and $12,372,275 in labor costs relative to the estimated baseline of continued transition year policies. The Quality Payment Program Year 2 reduction in burden based on proposals in this rule reflects several proposed policies, including our proposal for significant hardship or other type of exception, including a new significant hardship exception for small practices for the advancing care information performance category. Our burden estimates also reflect the proposed reduction in the length of the CAHPS survey; our proposal to allow clinicians that practice primarily in the hospital to elect to use facility-based measurements, thereby eliminating the need for additional quality data submission processes; and our proposal to allow MIPS eligible clinicians to form virtual groups, which would create efficiencies in data submission.

TABLE 84—PROPOSED ANNUAL RECORDKEEPING AND SUBMISSION REQUIREMENTS

	Respondents/ responses	Hours per response	Total annual burden hours	Labor cost of submission	Total annual burden cost
Registration for Virtual Groups	16	10.0	160	Varies (See Table 60)	$13,313
Election of Facility-Based Measurement	18,207	1.0	18,207	36.12	657,637
QCDR and Registries self-nomination	233	10.0	2,330	88.10	205,273
CAHPS Survey Vendor Application	15	10.0	150	88.10	13,215
(Quality Performance Category) Claims Submission Mechanism	364,002	17.8	6,479,236	Varies (See Table 68)	595,645,593
(Quality Performance Category) Qualified Registry or QCDR Submission Mechanisms.	88,501	9.1	803,855	Varies (See Table 69)	75,318,776
(Quality Performance Category) EHR-Submission Mechanism	61,070	10.0	610,700	Varies (See Table 70)	56,925,790

[42] The burden estimate for the CY 2017 Quality Payment Program final rule was 10,940,417 hours for a total labor cost of $1,349,763,999. For comparability for the burden estimate in this proposed rule, the burden estimate for the CY 2017 Quality Payment Program final rule has been updated using 2016 wages.

TABLE 84—PROPOSED ANNUAL RECORDKEEPING AND SUBMISSION REQUIREMENTS—Continued

	Respondents/ responses	Hours per response	Total annual burden hours	Labor cost of submission	Total annual burden cost
(Quality Performance Category) CMS Web Interface Submission Mechanism.	298	74.0	22,052	88.10	1,942,662
(Quality Performance Category) Registration and Enrollment for CMS Web Interface.	10	1.0	10	88.10	881
(CAHPS for MIPS Survey) Beneficiary Participation	132,307	0.22	29,108	23.86	694,612
(CAHPS for MIPS Survey) Group Registration	461	1.5	692	88.10	60,921
§ 414.1375 (Advancing Care Information) Performance Category Significant Hardships, including for small practices and decertification of EHRs.	50,689	0.5	25,345	88.10	2,232,850
(Advancing Care Information Performance Category) Data Submission.	288,721	3.0	866,163	88.10	76,308,960
(Improvement Activities Performance Category) Data Submission	524,488	1.00	524,488	88.10	46,207,393
(Improvement Activities Performance Category) Call for Activities	150	0.5	75	Varies (See Table 80)	10,796
(Partial Qualifying APM Participant (QP) Election)	17	0.3	4	88.10	375
Other Payer Advanced APM Identification: Other Payer Initiated Process.	300	10.0	3,000	88.10	264,300
(Physician Compare) Opt Out for Voluntary Participants	22,400	0.3	5,600	88.10	493,472
Total	1,551,885		9,391,175		856,996,819

O. 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. 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 proposed collections discussed in this section of the proposed rule, please visit our Web site 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 proposed rule and identify the rule (CMS–5522–P), the ICR's CFR citation, CMS ID number, and OMB control number (0938–1222 for CAHPS for MIPS and 0938–1314 for all other ICRs). ICR-related comments are due August 21, 2017.

We have invited public comments on the virtual group election process under a separate **Federal Register** Notice (82 FR 27257) published on June 14, 2017. ICR-comments related to virtual group election are due on or before August 14, 2017. Because of the statutory requirement for the virtual group election process to take place prior to the start of the 2018 MIPS performance period, we have an earlier deadline for public comments on the virtual group election process to allow for earlier approval date for that information collection.

IV. 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.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make statutorily required policy changes and other policy updates to the Merit-based Incentive Payment System (MIPS) established under MACRA as well as the policies related to the Advanced APM provisions of MACRA, which together are referred to as the Quality Payment Program. As required by MACRA, MIPS consolidates several quality programs, including components of the Medicare Electronic Health Record Incentive Program, the Physician Quality Reporting System (PQRS), and the Physician Value-Based Payment Modifier (VM) and Physician Feedback Program. The MACRA effectively ends these programs after CY 2018 and authorizes MIPS' operation beginning in CY 2019.

The Quality Payment Program is structured to improve care quality over time with input from clinicians, patients, and other stakeholders. We have sought and continue to seek feedback from the health care community through various public avenues such as listening sessions, request for information and rulemaking where we have received feedback that many clinical practices are still working towards implementing the Quality Payment Program. This proposed rule for Quality Payment Program Year 2 reflects this feedback and includes several proposals that extend transition year policies finalized in the CY 2017 Quality Payment Program final rule with comment period; however, we also include policies to begin ramping up to full implementation, since the performance threshold must be based on the mean or median of prior year performance under statute starting in the 2019 MIPS performance period (MIPS payment year 2021). Additionally, we address elements of MACRA that were not included in the first year of the program, including virtual groups, facility-based measurement, and improvement scoring. We also include proposals to continue implementing elements of MACRA that do not take effect in the first or second year of the Quality Payment Program, including policies related to the All-Payer Combination Option for the APM incentive.

B. Overall Impact

We have examined the impact 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 (February 2, 2013), the Regulatory Flexibility Act (Pub. L. 96–354 enacted September 19, 1980) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 14–04 enacted March 22, 1995), 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). 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, as discussed below in this section, that the Medicare Part B provisions included in this proposed rule will redistribute more than $173 million in budget neutral payments in the second performance year. In addition, this proposed rule will increase government outlays for the exceptional performance payment adjustments under MIPS ($500 million), and incentive payments to QPs (approximately $590–$800 million). Overall, this rule will transfer more than $1 billion in payment adjustments for MIPS eligible clinicians and incentive payments to QPs. Therefore, 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.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. As shown in the discussion of Table 84 in the Collection of Information section of this proposed rule, we estimate that this proposed rule would reduce the ICR burden by 132,620 hours and would result in a further reduction in burden costs of $12.4 million in the Quality Payment Program Year 2 relative to Quality Payment Program Year 1. As shown in the discussion of Regulatory Review Costs in section V.E. of this proposed rule, we estimate that total regulatory review costs associated with the Quality Payment Program would be approximately $4.8 million.

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. The RFA requires agencies to analyze options for regulatory relief of small entities. Note that Small Business Administration (SBA) standards for small entities differ than the definition of a small practice under MIPS finalized in the CY 2017 Quality Payment Program final rule under § 414.1305. The SBA standard for a small business is $11 million in average receipts for an office of clinicians and $7.5 million in average annual receipts for an office of other health practitioners. (For details, see the SBA's Web site at *http://www.sba.gov/content/table-smallbusiness-size-standards* (refer to the 620000 series)).

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities either by nonprofit status or by having annual revenues that qualify for small business status under the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this Regulatory Impact Analysis section as well as elsewhere in this proposed rule is intended to comply with the requirement for an Initial Regulatory Flexibility Analysis (IRFA).

As discussed below, approximately 572,000 MIPS eligible clinicians will be required to submit data under MIPS. As shown later in this analysis, however, potential reductions in Medicare Part B payment for MIPS eligible clinicians under the MIPS are a small percentage of their total Medicare Part B paid charges—5 percent in the 2020 payment year—though rising to as high as 9 percent in subsequent years. On average, clinicians' Medicare billings are only approximately 23 percent of their total revenue,[43] so even those MIPS eligible clinicians that receive a negative MIPS payment adjustment under MIPS would rarely face losses in excess of 3 percent of their total revenues, the HHS standard for determining whether an economic effect is ''significant.'' (In order to determine whether a rule meets the RFA threshold of ''significant'' impact, HHS has, for many years, used as a standard adverse effects that exceed 3 percent of either revenues or costs.) However, because there are so many affected MIPS eligible clinicians, even if only a small proportion is significantly adversely affected, the number could be ''substantial.'' Therefore, we are unable to conclude that an Initial Regulatory Flexibility Analysis (IRFA) is not required. Accordingly, the analysis and discussion provided in this section, as well as elsewhere in this final rule with comment period, together meet the requirements for an IRFA. We note that whether or not a particular MIPS eligible clinician or other eligible clinician is adversely affected would depend in large part on the performance of that MIPS eligible clinician or other eligible clinician, and that CMS will offer significant technical assistance to MIPS eligible clinicians and other eligible clinicians in meeting the new standards.

For the 2018 MIPS performance period, this proposed rule has several key proposals that will provide regulatory relief for clinicians and practices and help increase ways for successful participation. These include implementing virtual groups, raising the low volume threshold, continuing to allow the use of 2014 Edition CEHRT (Certified Electronic Health Record Technology), and adding a new significant hardship exception for the advancing care information performance category for MIPS eligible clinicians who are in small practices, as summarized in section I.D.4.c. of this proposed rule.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small hospitals located in rural areas. 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 hospital located in a rural area as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small hospitals located in rural areas.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector because participation in Medicare is voluntary and because physicians and other clinicians have multiple options as to how they will participate under MIPS and discretion over their performance. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare

[43] Based on National Health Expenditure Data, Physicians and Clinical Services Expenditures, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

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 effects on state and local governments, preempts state law, or otherwise has Federalism implications. We have outlined in section II.D.6.(a) of this proposed rule a payer-initiated identification process for identifying which payment arrangements qualify as Other Payer Advanced APMs. State Medicaid programs may elect to participate in the payer-initiated identification process. We do not believe any of these policies impose a substantial direct effect on the Medicaid program as participation in the Payer Initiated Determination Process is voluntary and use of the Eligible Clinician Initiated Determination Process is also voluntary.

We have prepared the following analysis, which together with the information provided in the rest of this proposed rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are implementing a variety of changes to our regulations, payments, or payment policies to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We note that many of the MIPS policies from the CY 2017 Quality Payment Program final rule were only defined for the 2017 MIPS performance period and 2019 MIPS payment year (including the performance threshold, the performance category reweighting policies, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2018 MIPS performance period and 2020 MIPS payment year if there were no new regulatory action. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Medicare Payments

Section 101 of the MACRA, (1) repeals the Sustainable Growth Rate (SGR) formula for physician payment updates in Medicare, and (2) requires that we establish MIPS for eligible clinicians under which the Secretary must use a MIPS eligible clinician's final score to determine and apply a MIPS payment adjustment factor to the clinician's Medicare Part B payments for a year.

The largest component of the MACRA costs is its replacement of scheduled reductions in physician payments with payment rates first frozen at 2015 levels and then increasing at a rate of 0.5 percent a year during CYs 2016 through 2019. The estimates in this RIA take those legislated rates as the baseline for the estimates we make as to the costs, benefits, and transfer effects of this proposed regulation, with some proposed data submission provisions for the 2018 MIPS performance period taking effect in 2018 and 2019, and the corresponding positive and negative payment adjustments taking effect in the 2020 MIPS payment year.

As required by the MACRA, overall payment rates for services for which payment is made under the PFS would remain at the 2019 level through 2025, but starting in 2019, the amounts paid to individual MIPS eligible clinicians and other eligible clinicians would be subject to adjustment through one of two mechanisms, depending on whether the clinician achieves the threshold for participation in Advanced APMs to be considered a Qualifying APM Participant (QP) or Partial QP, or is instead evaluated under the MIPS.

1. Estimated Incentive Payments to QPs in Advanced APMs

From 2019 through 2024, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs would receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year, as discussed in section II.D. of this proposed rule.

The APM Incentive Payment is separate from, and in addition to, the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B payments. Eligible clinicians who do not become QPs, but meet a slightly lower threshold to become Partial QPs for the year, may elect to report to MIPS and would then be scored under MIPS and receive a MIPS payment adjustment, but do not receive the APM Incentive Payment. For the 2018 Medicare QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who have at least 20 percent, but less than 25 percent, of their payments for Part B covered professional services through an Advanced APM Entity, or furnish Part B covered professional services to at least 10 percent, but less than 20 percent, of their Medicare beneficiaries through an Advanced APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive or negative. If an eligible clinician does not meet either the QP or Partial QP standards, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to their Part B payments in a payment year based on performance during a prior performance period. Although the MACRA amendments established overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the second payment year (2020) of the Quality Payment Program in detail. After 2020, while overall payment levels will be partially bounded, we have also acknowledged in the preamble that the Department will likely revise its quality and other payment measures and overall payment thresholds and other parameters as clinicians' behavior changes.

We estimate that between 180,000 and 245,000 eligible clinicians will become QPs, therefore be exempt from MIPS, and qualify for lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services, which are estimated to be between approximately $11,820 million and $15,770 million in the 2018 Quality Payment Program performance year. We estimate that the

aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs would be between approximately $590 and $800 million for the 2020 Quality Payment Program payment year. These estimates reflect longstanding HHS policy not to attempt to predict the effects of future rulemaking in order to maximize future Secretarial discretion over whether, and if so how, payment or other rules would be changed.

We project the number of eligible clinicians that will be excluded from MIPS as QPs using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect APMs that will be operating in 2018. This proposed rule indicates which APMs would be Advanced APMs under proposed policies, including the Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model, Comprehensive ESRD Care (CEC) Model, Episode Payment Models (EPM), Vermont All-Payer ACO Model,[44] Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangement), ACO Track 1+ Model, the Shared Savings Program Tracks 2 and 3. We also project Advanced APM participation based on applicant counts and estimated acceptance rates to Advanced APMs that had open application periods as of early 2017. We use a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016, for the first Medicare QP Performance Period for 2017. We examine the extent to which Advanced APM participants would meet the QP thresholds of having at least 25 percent of their Part B covered professional services or at least 20 percent of their Medicare beneficiaries furnished Part B covered professional services through the Advanced APM Entity. The preliminary version of this file followed the methodologies for group (APM Entity level) determination of QP status outlined in the CY 2017 Quality Payment Program final rule with comment period. We also assumed that during the first Medicare QP Performance Period, the majority of eligible clinicians participating in Advanced APMs would be QPs based on the preliminary version of this file.

2. Estimated Numbers of Clinicians Eligible for MIPS

Certain clinicians may not be eligible to participate or may be excluded from participation in MIPS for various reasons. For example, the MACRA requires us to limit eligibility for the 2019 and 2020 MIPS payment years to specified clinician types. Additionally, we exclude eligible clinicians with billings that do not exceed the low volume threshold as proposed in section II.C.2.c. of this proposed rule: Those with $90,000 or less in Part B allowed charges or 200 or fewer Medicare Part B patients as measured at the TIN/NPI level for individual reporting, the TIN level for group reporting, the APM Entity level for reporting under the APM scoring standard. We also exclude those who are newly enrolled to Medicare and those eligible clinicians who are QPs.

To estimate the number of clinicians that are not in MIPS due to an ineligible clinician type for CY 2018, our scoring model used the first 2019 Payment Year MIPS eligibility file as described in 81 FR 77069 and 77070. The data file included 1.5 million clinicians who had Medicare Part B claims from September 1, 2015 to August 31, 2016 and included a 60-day claim run-out. We limited our analysis to those clinicians identified as MIPS eligible clinician types for the 2020 MIPS payment year: Doctors of medicine, doctors of osteopathy, chiropractors, dentists, optometrists, podiatrists, nurse practitioners, physician assistants, certified registered nurse anesthetists, and clinical nurse specialists.

We estimated the number of clinicians excluded for low volume by comparing the allowed Medicare Part B charges in the first 2019 MIPS payment year eligibility file to the proposed low volume threshold. We used 2015 PQRS reporting data to determine whether clinicians have historically reported as a group and whether to make the low-volume determination at the individual (TIN/NPI) or group (TIN) level. We assumed all Shared Savings Program or Pioneer ACO participants would exceed the low volume threshold because the ACOs have a requirement for a minimum number of assigned beneficiaries.

Because of the lack of available data on which eligible clinicians would elect to participate as part of a virtual group under the policies proposed in section II.C.4 of this proposed rule, the scoring model does not reflect the proposed policies for scoring virtual groups.

We estimated the number of newly enrolled Medicare clinicians to be excluded from MIPS by assuming clinicians (NPIs) are newly enrolled if they have Part B charges in the eligibility file, but no Part B charges in 2015. Because of data limitations, this newly enrolled modeling methodology is different than the one that will be used under the policies finalized under §§ 414.1310 and 414.1315.

To exclude QPs from our scoring model, we used a preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016 for the first Medicare QP Performance Period for 2017 that included clinicians participating in Advanced APMs active as of mid-March 2017. We assumed that all partial QPs would participate in MIPS and included them in our scoring model. Because of the expected growth in Advanced APM participation, the estimated number of QPs excluded from our model based on data from the 2017 Quality Payment Program performance period (74,920) is lower than the summary level projection for the 2018 Quality Payment Program performance period based on the expected growth in APM participation (180,000–245,000). This expected growth is due in part to reopening of CPC+ and Next Generation ACO for 2018, and the ACO Track 1+ which is projected to have a large number of participants, with a large majority reaching QP status. Hence, our model may overestimate the fraction of clinicians and allowed Medicare Part B charges that will remain subject to MIPS after the exclusions.

We have estimated the cumulative effects of these exclusions in Table 85. We estimate that 65 percent of clinicians' $124,029 million in allowed Medicare Part B charges will be included in MIPS. Further, we estimate that approximately 37 percent of 1,548,022 Medicare clinicians billing to Part B will be included in MIPS.

Table 85 also shows the number of eligible clinicians remaining in the scoring model used for this regulatory impact analysis (554,846) is lower than the estimated number of eligible clinicians remaining after exclusions (572,299). The discrepancy is due to our scoring model excluding clinicians that submitted via measures groups under

[44] Vermont ACOs will be participating in an Advanced APM during 2018 through a modified version of the Next Generation ACO Model. The Vermont Medicare ACO Initiative will be an Advanced APM beginningin 2019.

the 2015 PQRS, since that data submission mechanism was eliminated under MIPS.

TABLE 85—PROJECTED NUMBER OF CLINICIANS INELIGIBLE FOR OR EXCLUDED FROM MIPS IN CY 2018, BY REASON *

Reason for exclusion	Count of Medicare clinicians (TIN/NPIs) remaining after exclusion	Part B allowed charges remaining after exclusion ($ in millions)	Count of Medicare clinicians (TIN/NPIs) excluded	Part B allowed charges excluded ($ in millions)
All Medicare clinicians billing Part B	1,548,022	$124,029	.....	.....
Subset to clinician types that are eligible for 2020 MIPS payment year **	1,314,733	$101,733	233,289	$22,296
Exclude newly enrolled clinicians ***	1,232,779	$101,243	81,954	$490
Additionally, exclude low volume clinicians ****	647,219	$87,147	585,560	$14,096
Additionally, exclude qualifying APM participants (QPs) *****	572,299	$80,658	74,920	$6,489
Total remaining in MIPS after exclusion	572,299	$80,658	.....	.....
Percent eligible clinicians remaining in MIPS after exclusions	37%	65%	.....	.....
Additional Exclusions for Scoring Model				
Exclude clinicians who previously submitted measures groups under 2015 PQRS	554,846	$71,930	17,453	$8,728
Percent eligible clinicans remaining in scoring model after exclusions	36%	58%	.....	.....

* Allowed Medicare Part B charges for covered services of the clinician under Part B from September 1, 2015 to August 31, 2016 data. Payments estimated using 2015 or 2016 dollars.

** Section 1848(q)(1)(C) of the Act defines a MIPS eligible clinician for payment years 1 and 2 as a physician, physician's assistant, nurse practitioner, or clinical nurse anesthetist, or a group that includes such clinicians.

*** Newly enrolled Medicare clinicians in our scoring model had positive Part B charges between September 1, 2015 and August 31, 2016 but had no Part B charges for CY2015.

**** Low-volume clinicians have less than or equal to $90,000 in allowed Medicare Part B charges or less than or equal to 200 Medicare patients.

***** QPs have at least 25 percent of their Medicare Part B covered professional services or least 20 percent of their Medicare beneficiaries furnished part B covered professional services through an Advanced APM.

3. Estimated Impacts on Payments to MIPS Eligible Clinicians

Our scoring model includes eligible clinicians who will be required to submit MIPS data to us in year 1.[45] They are eligible clinicians who (a) are not QPs participating in Advanced APMs, (b) exceeded the low volume threshold, and (c) enrolled as Medicare clinicians prior to the current performance year.

Payment impacts in this proposed rule reflect averages by specialty and practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the mix of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients. In addition, MIPS eligible clinicians may receive substantial Medicare revenues for services under other Medicare payment systems that would not be affected by MIPS payment adjustment factors.

To estimate the impact of MIPS on clinicians required to report, we used the most recently available data, including 2014 and 2015 PQRS data, 2014 and 2015 CAHPS for PQRS data, 2014 and 2015 VM data, 2015 and 2016 Medicare and Medicaid EHR Incentive Program data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*), preliminary version of the file used for the predictive qualifying Alternative Payment Model participants analysis made available on *qpp.cms.gov* on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016 for the first Medicare QP Performance Period for 2017, the 2017 MIPS published measure benchmarks, and other available data to model the scoring provisions described in this regulation. First, we arithmetically calculated a hypothetical final score for each MIPS eligible clinician based on quality, advancing care information, and improvement activities performance categories.

We estimated the quality performance category score using measures submitted to PQRS for the 2015 performance period. For quality measures submitted via the claims, EHR, qualified registry, QCDR, and CMS-approved survey vendor submission mechanisms, we applied the published benchmarks developed for the 2017 MIPS performance period. For quality measures submitted via Web Interface, we applied the published benchmarks developed for the 2017 Shared Savings Program where available, and did not calculate scores for measures for which Shared Savings Program benchmarks did not exist. For the all-cause hospital readmission measure we used the 2015 VM analytic file, which was the most recent data available, and calculated our own benchmarks based on 2015 data since published benchmarks were not yet available. In order to estimate the impact of improvement for the quality performance category, we estimated a quality performance category percent score using 2014 PQRS data, 2014 CAHPS for PQRS data, and 2014 VM data. Because we lack detailed information on which MIPS eligible clinicians would elect to submit as part of a virtual group and which MIPS eligible clinicians based primarily in inpatient hospital settings or in emergency departments would elect facility-based measurement, the proposed policies regarding virtual groups and facility-based measurement

[45] Due to data limitations, our scoring model excluded the 17.453 MIPS eligible clinicians who submitted quality via the measures groups mechanism under the 2015 PQRS. The measures group submission mechanism is not available in MIPS.

are not reflected in our scoring model. Our model applied the MIPS APM scoring standards proposed in section II.C.6.g. of this proposed rule to quality data from MIPS eligible clinicians that participated in the Shared Savings Program model in 2015.

We propose in section II.C.6.d.(2) of this proposed rule, for the cost performance category to have a zero percent weight and to not contribute to the 2020 MIPS payment year final score. Therefore, we did not include cost measures in this scoring model.

For the advancing care information performance category score, we used data from the 2015 Medicare and Medicaid EHR Incentive Programs. Because the EHR Incentive Programs are based on attestation at the NPI level, the advancing care information performance category scores are assigned to clinicians by their individual national provider identifier (NPI), regardless of whether the clinician was part of a group submission for PQRS. We assigned a score of 100 percent to MIPS eligible clinicians who attested in the 2015 Medicare EHR Incentive Program or received a 2015 incentive payment from the Medicaid EHR Incentive Program (after excluding incentive payments to adopt, implement, and upgrade). While we had attestation information for the Medicare EHR Incentive Program, we did not have detailed attestation information for the Medicaid EHR Incentive Program. Therefore, we used incentive payments (excluding the adopt implement and upgrade incentive payments) as a proxy for attestation in the Medicaid EHR Incentive Program. Our rationale for selecting a 100 percent performance score is that the requirements to achieve a base score of 50 percent in MIPS are lower than the EHR Incentive Program requirements to attest for meaningful use (which determined whether program requirements were met on an all or nothing basis). We anticipate clinicians who met EHR Incentive Program requirements for meaningful use will be able to achieve an advancing care information performance category score of 100 percent. Because the minimum requirements for meaningful use did not allow partial scoring, we believe the clinicians who met the minimum requirements would be able to achieve an advancing care information performance category score of 100 percent. For example, the minimum requirements to attest to Modified Stage 2 objectives and measures for the 2017 Medicare EHR Incentive Program (assuming no measure exceptions and an immunization registry is available) would translate into an advancing care information performance score of 85 percent. Generally, we see that clinicians have performance greater than the minimum requirements, which is the reason we estimated an advancing care information performance category score of 100 percent.

For those clinicians who did not attest in either the 2015 Medicare or Medicaid EHR Incentive Program, we evaluated whether the MIPS eligible clinician could have their advancing care information performance category score reweighted. The advancing care information performance category weight is set equal to zero percent, and the weight is redistributed to quality for non-patient facing clinicians, hospital-based clinicians, ASC-based clinicians, NPs, PAs, CRNAs, or CNSs, or those who request and are approved for a significant hardship or other type of exception, including a new significant hardship exception for small practices, or clinicians who are granted an exception based on decertified EHR technology. We used the non-patient facing and hospital-based indicators and specialty and small practice indicators as calculated in the initial MIPS eligibility run. Due to data limitations, we were not able to reweight the advancing care information performance category scores of ASC-based clinicians in our scoring model. For significant hardship exceptions, we used the 2016 final approved significant hardship file. If a MIPS eligible clinician did not attest and did not qualify for a reweighting of their advancing care information performance category, the advancing care information performance category score was set equal to zero percent.

We modeled the improvement activities performance category score based on 2015 APM participation and historic participation in 2015 PQRS and 2015 Medicare and Medicaid EHR Incentive Programs. Our model identified the 2015 Shared Savings Program participants and assigned them an improvement activity score of 100 percent, consistent with our policy to assign a 100 percent improvement activities performance category score to Shared Savings Program participants in Quality Payment Program Payment Year 2019. Due to limitations in 2015 data, our model did not include 2015 participants in APMs other than the Shared Savings Program.

Clinicians and groups not participating in a MIPS APM were assigned an improvement activities score based on their performance in the quality and advancing care information performance categories. MIPS eligible clinicians whose 2015 PQRS data meets all the MIPS quality submission criteria (for example, submitting 6 measures with data completeness, including one outcome or high priority measures) and had an estimated advancing care information performance category score of 100 percent (if advancing care information is applicable to them) are assigned an improvement activities performance category score of 100 percent. MIPS eligible clinicians who did not participate in 2015 PQRS or the 2015 Medicare or Medicaid EHR Incentive Program (if it was applicable), earned an improvement activity performance category score of zero percent, with the rationale that these clinicians may be less likely to participate in MIPS if they have not previously participated in other programs.

For the remaining MIPS eligible clinicians not assigned an improvement activities performance category score of 0 or 100 percent in our model, we assigned a score that corresponds to submitting one medium-weighted improvement activity. The MIPS eligible clinicians assigned an improvement activity performance category score corresponding to a medium-weighted activity include (a) those who submitted some quality measures under the 2015 PQRS but did not meet the MIPS quality submission criteria or (b) those who did not submit any quality data under the 2015 PQRS who attested under the Medicare EHR Incentive program or received an incentive payment (excluding adopt implement and upgrade payments) from the Medicaid EHR Incentive Program. We assumed that these clinicians may be likely to partially, but not fully participate, in the improvement activities category. For non-patient facing clinicians, clinicians in a small practice (consisting of 15 or fewer professionals), clinicians in practices located in a rural area, clinicians in a geographic healthcare professional shortage area (HPSA) practice or any combination thereof, the medium weighted improvement activity was assigned one-half of the total possible improvement activities performance category score (20 out of a 40 possible points or 50 percent) The remaining MIPS eligible clinicians not assigned an improvement activities performance category score of 0, 50, or 100 points were assigned a score corresponding to one medium-weighted activity (10 out of 40 possible points or 25 percent). Due to lack of available data, we were not able to identify MIPS eligible clinicians in patient-centered medical homes or comparable specialty societies in our scoring model. The

policy finalized under § 414.1380(b)(3) indicates that MIPS eligible clinicians in a patient centered medical home or a comparable specialty societies would qualify for improvement activities performance category score of 100 percent.

Our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, and multiplying the sum by 100 points. For MIPS eligible clinicians that had their advancing care information performance category score reweighted due to a significant hardship exception or automatic reweighting, the weight for the advancing care information performance category was assigned to the quality performance category.

The scoring model reflects the proposed bonuses for complex patients and small practices in sections II.C.7.b.(1)(b) and II.C.7.b.(1)(c) of this proposed rule. Consistent with the proposal to define complex patients as those with high medical risk, our scoring model adds the average Hierarchical Condition Category (HCC) score across all the MIPS eligible clinician's patients (with a cap of three points) to the final score. We used the average HCC risk score calculated for each NPI in the 2015 Physician and Other Supplier Public Use File. We also generated a group average HCC risk score by weighing the scores for individual clinicians in each group by the number of beneficiaries they have seen. Our scoring model also adds 5 points to the final score for small practices that had a final score greater than 0 points. After adding any applicable bonus for complex patients and small practices, we set any final scores that exceeded 100 points to 100.

We then implemented an exchange function based on the provisions of this proposed rule to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the estimated Medicare Part B paid charges. Due to data limitations, we assumed that the paid amount was 80 percent of Medicare Part B allowed charges. We iteratively modified the parameters of the exchange function distributions of MIPS payment adjustments that meet statutory requirements related to the linear sliding scale, budget neutrality and aggregate exceptional performance payment adjustment amounts (as finalized under § 414.1405). Our model used a 15-point performance threshold and a 70-point additional performance threshold.

With the extensive changes to policy and the flexibility that is allowed under MIPS, estimating impacts of this proposed rule using only historic 2015 participation assumptions would significantly overestimate the impact on clinicians, particularly on clinicians in practices with 1–15 clinicians, which have traditionally had lower participation rates. To assess the sensitivity of the impact to the participation rate, we have prepared two sets of analyses.

The first analysis, which we label as standard participation assumptions, relies on the assumption that a minimum 90 percent of MIPS eligible clinicians will participate in submitting quality performance category data to MIPS, regardless of practice size. Therefore, we assumed that, on average, the categories of practices with 1–15 clinicians would have 90 percent participation in the quality performance category. This assumption is an increase from existing historical data. PQRS participation rates have increased steadily since the program began; the 2015 PQRS Experience Report showed an increase in the participation rate from 15 percent in 2007 to 69 percent in 2015.[46] In 2015, among those eligible for MIPS, 88.7 percent participated in the PQRS. In 2015, MIPS eligible practices of less than 1–15 clinicians participated in the PQRS at a rate of 69.7 percent. Because practices of 16–24 have a 91.7 percent participation rate based on historical data, and 25–99 clinicians have a 96.2 percent participation rate and practices of 100+ clinicians have a 99.4 percent participation rate, we assumed the average participation rates of those categories of clinicians would be the same as under the 2015 PQRS. Our assumption of 90 percent average participation for the categories of practices with 1–15 clinicians reflects our belief that small and solo practices will respond to the finalized policies and this proposed rule's flexibility, reduced data submission burden, financial incentives, and the support they will receive through technical assistance by participating at a rate close to that of other practice sizes, enhancing the existing upward trend in quality data submission rates. Therefore, we assume that the quality scores assigned to new participants reflect the distribution of MIPS quality scores. We also applied behavioral participation assumptions to the improvement activities performance category.

To simulate the impact of the standard model assumption, we randomly select a subset of non-participants and substitute the quality and improvement activity scores of randomly selected participants. For example, for a previously non-participating clinician, we substitute the scores of a randomly selected MIPS eligible clinician with a quality score of 73 percent. The improvement activities performance category score is then computed using this alternative quality score. We did not apply the same participation assumptions to the advancing care information performance category because the category applies only to a subset of MIPS eligible clinicians, and, as noted above, would be weighted at zero percent for non-patient facing clinicians, hospital-based clinicians, ASC-based clinicians, NPs, PAs, CRNAs, or CNSs, and those who request and are approved for a significant hardship or other type of exception, including those in small practices. Further, we took into account that advancing care information performance category participation may be affected by the cost and time it may take to acquire and implement certified EHR technology needed to perform in that performance category.

The second analysis, which we label as ''alternative participation assumptions,'' assumes a minimum participation rate in the quality and improvement activities performance categories of 80 percent. Because the 2015 PQRS participation rates for practices of more than 15 clinicians are greater than 80 percent, this analysis assumes increased participation for practices of 1–15 clinicians only. Practices of more than 15 clinicians are included in the model at their historic participation rates.

Table 86 summarizes the impact on Part B services of MIPS eligible clinicians by specialty for the standard participation assumptions.

Table 87 summarizes the impact on Part B services of MIPS eligible clinicians by specialty under the alternative participation assumptions.

Tables 89 and 90 summarize the impact on Part B services of MIPS eligible clinicians by practice size for the standard participation assumptions (Table 88) and the alternative participation assumptions (Table 89).

Tables 87 and 89 show that under our standard participation assumptions, the vast majority (96.1 percent) of MIPS eligible clinicians are anticipated to receive positive or neutral payment adjustments for the 2020 MIPS payment

[46] 2015 PQRS Experience Report, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf.*

year, with only 3.9 percent receiving negative MIPS payment adjustments. Using the alternative participation assumptions, Tables 88 and 90 show that 94.3 percent of MIPS eligible clinicians are expected to receive positive or neutral payment adjustments.

The projected distribution of funds reflects this proposed rule's emphasis on increasing more complete reporting of MIPS eligible clinicians for the Quality Payment Program Performance Year 2, which continues the ramp to more robust participation in future MIPS performance years.

TABLE 86—MIPS ESTIMATED PAYMENT YEAR 2020 IMPACT ON ESTIMATED PAID AMOUNT BY SPECIALTY, STANDARD PARTICIPATION ASSUMPTIONS *

Provider type, specialty	Number of MIPS eligible clinicians	Estimated paid amount (mil) (80% of allowed charges) **	Percent eligible clinicians engaging with quality reporting	Percent eligible clinicians with positive or neutral payment adjustment	Percent eligible clinicians with exceptional payment adjustment	Percent eligible clinicians with negative payment adjustment	Aggregate impact positive adjustment (mil) **	Aggregate impact negative payment adjustment (mil) **	Combined impact of negative and positive adjustments and exceptional performance payment as percent of estimated paid amount (%)
Overall	554,846	$57,544	96.6	96.1	76.8	3.9	673.3	−173.3	0.9
Addiction Medicine	71	3	95.8	95.8	82.4	4.2	0.0	0.0	−0.2
Allergy/Immunology	1,692	162	94.9	94.9	80.0	5.1	1.8	−0.8	0.6
Anesthesiology	14,105	789	97.8	95.7	74.5	4.3	7.8	−3.0	0.6
Anesthesiology Assistant	588	7	100.0	99.8	88.4	0.2	0.1	0.0	1.7
Cardiac Electrophysiology	1,970	341	97.5	98.4	81.5	1.6	4.7	−0.4	1.3
Cardiac Surgery	1,181	182	98.6	98.3	85.2	1.7	2.7	−0.2	1.4
Cardiovascular Disease (Cardiology)	20,025	3,600	96.5	96.8	80.9	3.2	47.2	−8.5	1.1
Certified Clinical Nurse Specialist	896	22	97.0	96.4	86.2	3.6	0.3	−0.2	0.4
Certified Registered Nurse Anesthetist (CRNA)	16,600	259	99.3	98.0	84.7	2.0	3.1	−0.7	0.9
Chiropractic	581	31	92.9	92.6	52.4	7.4	0.2	−0.2	−0.1
Clinic or Group Practice	393	51	97.7	97.2	96.9	2.8	0.9	−0.4	1.0
Colorectal Surgery (Proctology)	1,046	97	95.7	96.2	75.6	3.8	1.2	−0.3	0.9
Critical Care (Intensivists)	2,730	201	97.0	96.6	82.9	3.4	2.5	−0.7	0.9
Dermatology	9,506	2,510	91.8	91.8	69.6	8.2	27.2	−10.7	0.7
Diagnostic Radiology	27,990	3,317	97.0	95.7	58.8	4.3	26.3	−6.8	0.6
Emergency Medicine	31,503	1,728	99.1	97.4	56.2	2.6	12.8	−2.2	0.6
Endocrinology	4,376	336	97.3	97.2	80.1	2.8	4.3	−1.0	1.0
Family Medicine ***	54,171	3,667	97.0	96.9	80.7	3.1	48.1	−11.1	1.0
Gastroenterology	10,910	1,204	96.0	96.5	79.2	3.5	15.6	−2.8	1.1
General Practice	2,210	214	91.3	90.7	74.7	9.3	1.9	−1.7	0.1
General Surgery	14,135	1,143	96.6	96.6	79.4	3.4	13.9	−3.5	0.9
Geriatric Medicine	1,394	121	96.4	95.9	77.0	4.1	1.4	−0.5	0.8
Geriatric Psychiatry	119	9	91.6	89.9	76.6	10.1	0.1	−0.1	−0.7
Gynecological Oncology	807	80	98.4	98.3	79.4	1.7	1.0	−0.1	1.0
Hand Surgery	1,037	131	92.8	92.3	67.8	7.7	1.3	−0.5	0.6
Hematology	648	109	98.6	98.9	83.5	1.1	1.5	0.0	1.4
Hematology-Oncology	6,463	2,929	97.5	97.2	77.3	2.8	32.4	−4.5	1.0
Hospice and Palliative Care	645	23	99.5	99.1	88.1	0.9	0.3	0.0	1.3
Infectious Disease	4,571	497	94.2	94.1	78.9	5.9	5.6	−2.7	0.6
Internal Medicine	72,692	6,917	95.9	95.3	80.0	4.7	86.1	−24.7	0.9
Interventional Cardiology	2,716	491	97.5	98.5	83.8	1.5	7.1	−0.4	1.3
Interventional Pain Management	1,255	333	90.0	89.0	62.8	11.0	3.2	−1.9	0.4
Interventional Radiology	1,181	232	97.0	96.1	67.9	3.9	1.8	−0.5	0.6
Maxillofacial Surgery	194	5	99.0	99.0	85.4	1.0	0.1	0.0	1.0
Medical Oncology	2,530	870	98.5	98.4	78.2	1.6	9.3	−0.8	1.0
Nephrology	5,707	1,073	95.1	95.2	78.2	4.8	12.9	−3.0	0.9
Neurology	11,588	1,141	95.3	95.7	77.8	4.3	12.9	−5.4	0.7
Neuropsychiatry	67	6	91.0	91.0	72.1	9.0	0.0	−0.1	−0.2
Neurosurgery	3,850	505	95.3	95.2	72.9	4.8	5.5	−1.8	0.7
Nuclear Medicine	466	66	97.0	97.2	81.2	2.8	0.7	−0.3	0.7
Nurse Practitioner	50,649	1,313	98.0	97.8	87.3	2.2	16.7	−7.0	0.7
Obstetrics & Gynecology	15,587	237	99.0	99.1	88.3	0.9	3.0	−0.6	1.0
Ophthalmology	14,779	6,451	96.8	96.6	73.6	3.4	99.0	−5.9	1.4
Optometry	4,621	439	94.5	94.3	69.2	5.7	5.0	−1.5	0.8
Oral Surgery (Dentist only)	282	7	97.5	97.9	89.1	2.1	0.1	−0.1	−0.4
Orthopedic Surgery	17,504	2,586	93.4	93.3	66.8	6.7	25.2	−9.9	0.6
Osteopathic Manipulative Medicine	297	22	96.0	94.9	79.1	5.1	0.2	−0.1	0.7
Otolaryngology	6,854	777	93.7	92.5	68.5	7.5	7.5	−3.6	0.5
Pain Management	1,475	291	88.1	86.6	63.4	13.4	2.6	−2.0	0.2
Pathology	7,924	770	96.6	95.5	65.0	4.5	6.1	−4.2	0.2
Pediatric Medicine	4,007	43	99.6	99.6	90.2	0.4	0.5	−0.1	1.1
Peripheral Vascular Disease	57	7	98.2	96.5	90.9	3.5	0.1	0.0	1.0
Physical Medicine and Rehabilitation	5,237	734	91.3	90.5	68.4	9.5	6.4	−5.0	0.2
Physician Assistant	38,378	875	98.7	98.4	84.1	1.6	11.2	−3.0	0.9
Physician, Sleep Medicine	256	18	96.5	97.7	80.8	2.3	0.2	0.0	0.9
Plastic and Reconstructive Surgery	1,986	170	94.7	94.7	77.5	5.3	1.8	−1.0	0.4
Podiatry	9,558	1,231	87.3	87.0	59.2	13.0	10.0	−9.1	0.1
Preventive Medicine	221	11	98.2	97.7	83.8	2.3	0.1	0.0	0.8
Psychiatry	10,590	487	93.9	93.7	75.2	6.3	4.2	−4.8	−0.1
Pulmonary Disease	8,756	1,111	96.2	96.2	80.0	3.8	13.8	−3.4	0.9
Radiation Oncology	3,049	810	97.9	97.3	80.8	2.7	9.0	−1.6	0.9
Rheumatology	3,340	1,126	97.2	97.2	80.5	2.8	15.0	−2.0	1.2
Sports Medicine	792	61	97.0	96.8	78.7	3.2	0.7	−0.1	0.9
Surgical Oncology	713	52	98.6	98.9	82.7	1.1	0.7	−0.1	1.2
Thoracic Surgery	1,738	203	97.8	98.1	82.9	1.9	2.8	−0.3	1.2
Other	272	34	94.9	95.6	84.6	4.4	0.4	−0.1	0.9
Urology	8,590	1,596	95.4	96.1	72.4	3.9	17.9	−3.4	0.9
Vascular Surgery	2,725	683	95.8	96.0	73.9	4.0	7.5	−2.1	0.8

Notes:
* Standard scoring model assumes that a minimum of 90 percent of clinicians within each practice size category would participate in quality data submission.

** 2014, 2015 and 2016 data used to estimate 2018 payment adjustments. Payments estimated using 2015 and 2016 dollars.
*** Specialty descriptions as self-reported on Part B claims. Note that all categories are mutually exclusive, including General Practice and Family Practice. 'Family Medicine' is used here for physicians listed as 'Family Practice' in Part B claims.

TABLE 87—MIPS ESTIMATED PAYMENT YEAR 2020 IMPACT ON ESTIMATED PAID AMOUNT BY SPECIALTY, ALTERNATIVE PARTICIPATION ASSUMPTIONS *

Clinician specialty/type	Number of MIPS eligible clinicians	Estimated paid amount (mil) (80% of allowed charges) **	Percent eligible clinicians engaging with quality reporting	Percent eligible clinicians with positive or neutral payment adjustment	Percent eligible clinicians with exceptional payment adjustment	Percent eligible clinicians with negative payment adjustment	Aggregate impact positive adjustment (mil) **	Aggregate impact negative payment adjustment (mil) **	Combined impact of negative and positive adjustments and exceptional performance payment as percent of estimated paid amount (%)
Overall	554,846	$57,544	94.5	94.3	77.1	5.7	782.9	−282.9	0.9
Addiction Medicine	71	3	94.4	94.4	83.6	5.6	0.0	0.0	−0.2
Allergy/Immunology	1,692	162	89.4	90.0	80.5	10.0	2.0	−1.5	0.3
Anesthesiology	14,105	789	96.8	94.8	74.5	5.2	9.0	−4.5	0.6
Anesthesiology Assistant	588	7	100.0	99.8	88.4	0.2	0.1	0.0	2.0
Cardiac Electrophysiology	1,970	341	96.9	98.0	81.6	2.0	5.6	−0.5	1.5
Cardiac Surgery	1,181	182	97.5	97.3	85.6	2.7	3.2	−0.4	1.6
Cardiovascular Disease (Cardiology)	20,025	3,600	94.1	94.9	81.2	5.1	54.8	−15.4	1.1
Certified Clinical Nurse Specialist	896	22	96.0	95.4	86.3	4.6	0.3	−0.2	0.3
Certified Registered Nurse Anesthetist (CRNA)	16,600	259	98.9	97.6	84.8	2.4	3.6	−1.1	1.0
Chiropractic	581	31	85.0	86.1	51.2	13.9	0.1	−0.4	−0.8
Clinic or Group Practice	393	51	97.2	96.7	96.8	3.3	1.0	−0.4	1.2
Colorectal Surgery (Proctology)	1,046	97	92.9	94.3	75.4	5.7	1.4	−0.4	0.9
Critical Care (Intensivists)	2,730	201	95.9	95.7	83.2	4.3	3.0	−0.9	1.0
Dermatology	9,506	2,510	85.3	85.9	69.9	14.1	31.0	−17.9	0.5
Diagnostic Radiology	27,990	3,317	96.2	94.9	58.8	5.1	32.0	−9.3	0.7
Emergency Medicine	31,503	1,728	98.8	97.2	56.2	2.8	15.6	−2.9	0.7
Endocrinology	4,376	336	94.8	95.1	80.6	4.9	5.0	−1.9	0.9
Family Medicine ***	54,171	3,667	95.2	95.3	80.9	4.7	55.7	−18.3	1.0
Gastroenterology	10,910	1,204	93.5	94.4	79.5	5.6	18.2	−4.8	1.1
General Practice	2,210	214	83.6	83.9	75.9	16.1	1.8	−3.4	−0.7
General Surgery	14,135	1,143	94.3	94.4	79.7	5.6	16.1	−5.9	0.9
Geriatric Medicine	1,394	121	94.3	94.0	77.3	6.0	1.6	−0.8	0.7
Geriatric Psychiatry	119	9	87.4	86.6	76.7	13.4	0.1	−0.1	−0.8
Gynecological Oncology	807	80	98.0	97.9	79.5	2.1	1.2	−0.2	1.3
Hand Surgery	1,037	131	89.9	90.0	67.7	10.0	1.5	−0.7	0.7
Hematology	648	109	98.0	98.3	83.7	1.7	1.8	−0.2	1.5
Hematology-Oncology	6,463	2,929	96.3	96.3	77.3	3.7	38.6	−6.0	1.1
Hospice and Palliative Care	645	23	99.4	98.9	88.1	1.1	0.4	0.0	1.6
Infectious Disease	4,571	497	89.8	90.1	79.3	9.9	6.2	−4.9	0.3
Internal Medicine	72,692	6,917	93.5	93.1	80.3	6.9	99.0	−40.6	0.8
Interventional Cardiology	2,716	491	97.0	98.2	83.8	1.8	8.4	−0.6	1.6
Interventional Pain Management	1,255	333	83.3	83.2	61.9	16.8	3.6	−3.1	0.1
Interventional Radiology	1,181	232	95.9	94.9	68.2	5.1	2.3	−0.8	0.6
Maxillofacial Surgery	194	5	98.5	98.5	85.9	1.5	0.1	0.0	1.1
Medical Oncology	2,530	870	98.0	97.8	78.3	2.2	11.2	−1.1	1.2
Nephrology	5,707	1,073	91.7	92.3	78.5	7.7	14.9	−5.6	0.9
Neurology	11,588	1,141	92.1	92.9	78.0	7.1	14.5	−9.0	0.5
Neuropsychiatry	67	6	91.0	91.0	72.1	9.0	0.1	−0.1	0.0
Neurosurgery	3,850	505	92.7	92.8	73.2	7.2	6.4	−2.8	0.7
Nuclear Medicine	466	66	94.0	94.4	81.6	5.6	0.8	−0.5	0.5
Nurse Practitioner	50,649	1,313	97.2	97.1	87.5	2.9	19.3	−9.8	0.7
Obstetrics & Gynecology	15,587	237	98.6	98.8	88.4	1.2	3.6	−1.0	1.1
Ophthalmology	14,779	6,451	94.0	94.0	73.9	6.0	117.0	−11.1	1.6
Optometry	4,621	439	90.8	91.0	69.6	9.0	5.8	−2.6	0.7
Oral Surgery (Dentist only)	282	7	96.5	96.8	89.4	3.2	0.1	−0.1	−0.8
Orthopedic Surgery	17,504	2,586	90.1	90.4	66.7	9.6	29.3	−15.2	0.5
Osteopathic Manipulative Medicine	297	22	93.9	93.6	79.1	6.4	0.3	−0.1	0.7
Otolaryngology	6,854	777	88.8	88.3	68.5	11.7	8.4	−6.3	0.3
Pain Management	1,475	291	82.2	81.6	62.9	18.4	2.8	−3.2	−0.1
Pathology	7,924	770	95.1	94.0	65.2	6.0	7.1	−5.4	0.2
Pediatric Medicine	4,007	43	99.5	99.5	90.2	0.5	0.6	−0.1	1.2
Peripheral Vascular Disease	57	7	94.7	94.7	90.7	5.3	0.1	0.0	0.9
Physical Medicine and Rehabilitation	5,237	734	86.0	85.7	68.5	14.3	7.0	−8.0	−0.1
Physician Assistant	38,378	875	98.2	97.9	84.2	2.1	13.2	−4.3	1.0
Physician, Sleep Medicine	256	18	95.7	96.9	81.0	3.1	0.3	−0.1	1.1
Plastic and Reconstructive Surgery	1,986	170	90.9	91.5	77.6	8.5	1.9	−1.6	0.2
Podiatry	9,558	1,231	76.1	77.0	58.4	23.0	10.1	−16.9	−0.5
Preventive Medicine	221	11	95.9	95.5	84.8	4.5	0.1	−0.1	0.6
Psychiatry	10,590	487	90.1	90.3	75.8	9.7	4.3	−7.9	−0.7
Pulmonary Disease	8,756	1,111	93.4	93.8	80.3	6.2	15.9	−5.9	0.9
Radiation Oncology	3,049	810	96.9	96.4	80.9	3.6	10.8	−2.2	1.1
Rheumatology	3,340	1,126	95.0	95.5	80.5	4.5	17.6	−3.5	1.3
Sports Medicine	792	61	96.5	96.3	78.9	3.7	0.8	−0.2	1.1
Surgical Oncology	713	52	98.2	98.5	82.6	1.5	0.8	−0.1	1.4
Thoracic Surgery	1,738	203	96.4	97.0	83.0	3.0	3.3	−0.6	1.3
Other	272	34	93.8	94.5	84.4	5.5	0.5	−0.2	1.0
Urology	8,590	1,596	92.9	93.9	72.5	6.1	21.2	−5.7	1.0
Vascular Surgery	2,725	683	93.1	93.8	73.8	6.2	8.6	−3.6	0.7

* Alternative scoring model assumes that a minimum of 80 percent of clinicians within each practice size category would participate in quality data submission.
** 2014, 2015 and 2016 data used to estimate 2018 payment adjustments. Payments estimated using 2015 and 2016 dollars.
*** Specialty descriptions as self-reported on Part B claims. Note that all categories are mutually exclusive, including General Practice and Family Practice. 'Family Medicine' is used here for physicians listed as 'Family Practice' in Part B claims.

TABLE 88—MIPS ESTIMATED PAYMENT YEAR 2020 IMPACT ON TOTAL ESTIMATED PAID AMOUNT BY PRACTICE SIZE, STANDARD PARTICIPATION ASSUMPTIONS *

Practice size	Number of MIPS eligible clinicians	Estimated paid amount (mil) (80% of allowed charges) **	Percent eligible clinicians engaging with quality reporting	Percent eligible clinicians with positive or neutral payment adjustment	Percent eligible clinicians with exceptional payment adjustment	Percent eligible clinicians with negative payment adjustment	Aggregate impact positive adjustment (mil) **	Aggregate impact negative payment adjustment (mil) **	Combined impact of negative and positive adjustments and exceptional performance payment as percent of estimated paid amount (%)
All practice sizes	554,846	$57,544	96.6	96.1	76.8	3.9	673.3	−173.3	0.9
1–15 clinicians	114,424	26,091	90.0	90.0	64.2	10.0	288.2	−115.1	0.7
16–24 clinicians	22,296	3,840	91.7	89.1	52.7	10.9	32.7	−17.9	0.4
25–99 clinicians	99,285	9,814	96.2	94.9	63.7	5.1	94.3	−29.9	0.7
100 or more clinicians	318,841	17,799	99.4	99.2	86.4	0.8	258.1	−10.4	1.4

Practice size is the total number of TIN/NPIs in a TIN.
* Standard scoring model assumes that a minimum of 90 percent of clinicians within each practice size category would participate in quality data submission.
** 2014, 2015 and 2016 data used to estimate 2018 payment adjustments. Payments estimated using 2015 and 2016 dollars.

TABLE 89—MIPS ESTIMATED PAYMENT YEAR 2020 IMPACT ON ESTIMATED PAID AMOUNT BY PRACTICE SIZE, ALTERNATE PARTICIPATION ASSUMPTIONS *

Practice size	Number of MIPS eligible clinicians	Estimated paid amount (mil) (80% of allowed charges)	Percent eligible clinicians engaging with quality reporting	Percent eligible clinicians with positive or neutral payment adjustment	Percent eligible clinicians with exceptional payment adjustment	Percent eligible clinicians with negative payment adjustment	Aggregate impact positive adjustment (mil) **	Aggregate impact negative payment adjustment (mil) **	Combined impact of negative and positive adjustments and exceptional performance payment as percent of estimated paid amount (%)
All practice sizes	554,846	$57,544	94.5	94.3	77.1	5.7	782.9	−282.9	0.9
1–15 clinicians	114,424	26,091	80.0	81.2	64.1	18.8	317.4	−224.7	0.4
16–24 clinicians	22,296	3,840	91.7	89.1	52.7	10.9	40.3	−17.9	0.6
25–99 clinicians	99,285	9,814	96.2	94.9	63.7	5.1	115.2	−29.9	0.9
100 or more clinicians	318,841	17,799	99.4	99.2	86.4	0.8	310.0	−10.4	1.7

Practice size is the total number of TIN/NPIs in a TIN.
* Alternative scoring model assumes that a minimum of 80 percent of clinicians within each practice size category would participate in quality data submission.
** 2014, 2015 and 2016 data used to estimate 2018 payment adjustments. Payments estimated using 2015 and 2016 dollars.

4. Potential Costs of Advancing Care Information and Improvement Activities for Eligible Clinicians

We believe that most MIPS eligible clinicians who can report the advancing care information performance category of MIPS have already adopted an EHR during Stage 1 and 2 of the Medicare or Medicaid EHR Incentive Programs, and will have limited additional operational expenses related to compliance with the advancing care information performance category requirements.

MIPS eligible clinicians who did not participate in the Medicare and Medicaid EHR Incentive Programs could potentially face additional operational expenses for implementation and compliance with the advancing care information performance category requirements.

For some MIPS eligible clinicians, the advancing care information performance category will be weighted at zero percent of the final score. We will continue our policy that was finalized in § 414.1375(a) to reweight the advancing care information performance category scores for certain MIPS eligible clinicians, including those who may have been exempt from the Medicare EHR Incentive Program such as hospital-based clinicians, non-patient facing clinicians, PAs, NPs, CNs and CRNAs. Further, as described in section II.6.f.(7)(a)(iv) of this proposed rule, we are proposing to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, to assign a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ambulatory surgical centers (ASCs). As described in section II.6.f.(7)(a)(i) of this proposed rule, we are proposing to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, to allow MIPS eligible clinicians to apply for a significant hardship exception and subsequently have their advancing care information performance category reweighted to zero when they are faced with a significant hardship. Relying on this same authority, we are also proposing a significant hardship exception for the advancing care information performance category for MIPS eligible clinicians who are in small practices, as discussed in section II.6.f.7.(a)(ii) of this proposed rule, and are proposing an exception for MIPS eligible clinicians whose CEHRT has been decertified under ONC's Health IT Certification Program as discussed in section II.6.f.7.(a)(v) of this proposed rule. Additionally, we believe most MIPS eligible clinicians who can report the advancing care information performance category of MIPS have already adopted an EHR during Stage 1 and 2 of the Medicare EHR Incentive Program. As we have stated with respect to the Medicare EHR Incentive Program, we believe that future retrospective studies on the costs to implement an EHR and the return on investment (ROI) will demonstrate efficiency improvements that offset the actual costs incurred by MIPS eligible clinicians participating in MIPS and specifically in the advancing care information performance category, but we are unable to quantify those costs and benefits at this time. At present, evidence on EHR benefits in either improving quality of care or reducing health care costs is mixed. This is not surprising since the adoption of EHR as a fully functioning part of medical practice is progressing, with numerous areas of adoption, use, and

sophistication demonstrating need for improvement. Even physicians and hospitals that can meet Medicare EHR Incentive Program standards have not necessarily fully implemented all the functionality of their systems or fully exploited the diagnostic, prescribing, and coordination of care capabilities that these systems promise. Moreover, many of the most important benefits of EHR depend on interoperability among systems and this functionality is still lacking in many EHR systems.

A recent RAND report prepared for the ONC reviewed 236 recent studies that related the use of health IT to quality, safety, and efficacy in ambulatory and non-ambulatory care settings and found that—

''A majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. These studies evaluated several forms of health IT: Metric of satisfaction, care process, and cost and health outcomes across many different care settings. Our findings agree with previous [research] suggesting that health IT, particularly those functionalities included in the Medicare EHR Incentive Program regulation, can improve healthcare quality and safety. The relationship between health IT and [health care] efficiency is complex and remains poorly documented or understood, particularly in terms of healthcare costs, which are highly dependent upon the care delivery and financial context in which the technology is implemented.'' [47] Other recent studies have not found definitive quantitative evidence of benefits.[48] Health IT vendors may face additional costs in Quality Payment Program Year 2 if they choose to develop additional capabilities in their systems to submit advancing care information and improvement activities performance category data on behalf of MIPS eligible clinicians. We request comments that provide information that would enable us to quantify the costs, costs savings, and benefits associated with implementation and compliance with the requirements of the advancing care information performance category.

Similarly, the costs for implementation and complying with the improvement activities performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices, including for some activities or certified patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per member per month.

Costs may vary based on panel size and location of practice among other variables. For example, Magill (2015) conducted a study of certified patient-centered medical home practices in two states.[49] That study found that costs associated with a full-time equivalent primary care clinician, who were associated with certified patient-centered medical home practices, varied across practices. Specifically, the study found an average cost of $7,691 per month in Utah practices, and an average of $9,658 in Colorado practices. Consequently, certified patient-centered medical home practices incremental costs per encounter were $32.71 in Utah and $36.68 in Colorado (Magill, 2015). The study also found that the average estimated cost per member, per month, for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. However, given the lack of comprehensive historical data for improvement activities, we are unable to quantify those costs in detail at this time. We request comments that provide information that would enable us to quantify the costs, costs savings, and benefits associated implementation of improvement activities.

D. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that the changes may have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. More broadly, we expect that over time clinician engagement in the Quality Payment Program may result in improved quality of patient care, resulting in lower morbidity and mortality. We believe the policies finalized in the CY 2017 Quality Payment Program final rule, as well as policies in this rule will lead to additional growth in the participation of both MIPS APMS and Advanced APMs. APMs promote seamless integration by way of their payment methodology and design that incentivize such care coordination. The policies that are being proposed regarding the All-Payer Combination Option and identification of Other Payer Advanced APMs will help facilitate both the development and participation in alternative payment arrangements in the private and public sectors. Clinicians can focus their efforts around the care transformation in either Advanced APM or MIPS APM models and know that those efforts will be aligned with the Quality Payment Program, either through incentive payments for QPs or through MIPS scores calculated based on performance within the APM assessed at the APM Entity level.

Several Advanced APMs and MIPS APMS have shown evidence of improving the quality of care provided to beneficiaries and beneficiaries' experience of care. For example, the various shared savings initiatives already operating have demonstrated the potential for quality programs to delivers better quality healthcare, smarter spending, and to put beneficiary experience at the center. For example, in August of 2015, we issued 2014 quality and financial performance results showing that ACOs continue to improve the quality of care for Medicare beneficiaries while generating net savings to the Medicare trust fund, if shared savings paid out to these ACOs are not included.[50] In 2014, the 20 ACOs in the Pioneer ACO Model and 333 Shared Shavings Program ACOs generated more than $411 million in total savings, which includes all ACOs' savings and losses but does not include shared savings payments to ACOs. Additionally, in their first years of implementation, both Pioneer and Shared Savings Program ACOs had higher quality care than Medicare FFS providers on measures for which comparable data were available. Shared Savings Program patients with multiple chronic conditions and with high predicted Medicare spending received better quality care than comparable FFS patients.[51] Between the first and fourth performance periods, Pioneer ACOs improved their average quality score from 71 percent to 92 percent. The Shared Savings Program ACOs yielded $465 million in savings to the Medicare Trust Funds in 2014, not including shared savings payments paid out to

[47] Paul G. Shekelle, et al. Health Information Technology: An Updated Systematic Review with a Focus on Meaningful Use Functionalities. RAND Corporation. 2014.

[48] See, for example, Saurabh Rahurkar, et al., ''Despite the Spread of Health Information Exchange, There Is Little Information of Its Impact On Cost, Use, And Quality of Care,'' Health Affairs, March 2015; and Hemant K. Bharga and Abhay Nath Mishra, ''Electronic Medical Records and Physician Productivity: Evidence from Panel Data Analysis,'' Management Science, July 2014.

[49] Magill et al. ''The Cost of Sustaining a Patient-Centered Medical Home: Experience from 2 States.'' Annals of Family Medicine, 2015; 13:429–435.

[50] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Factsheets-items/2015-08-25.html.*

[51] J.M. McWilliams et al., ''Changes in Patients' Experiences in Medicare Accountable Care Organizations.'' New England Journal of Medicine 2014; 371:1715–1724, DOI: 10.1056/NEJMsa1406552.

ACOs.[52] The Shared Savings Program ACOs generated total program savings (inclusive of all savings and losses relative to financial benchmarks, though not including shared savings payments) of $429 million for performance year 2015 (PY15).[53] Of participating ACOs, 119 Shared Savings Program ACOs earned shared savings by holding spending far enough below their financial benchmarks and meeting quality standards. No Track 2 ACOs owed CMS losses. The financial results were that for (PY15), 83 ACOs had expenditures lower than their benchmark, but did not qualify for shared savings, as they did not meet the minimum savings rate (MSR), and an increasing proportion of ACOs have generated savings above their MSR each year. For PY15, 31 percent of ACOs (120 of 392) generated savings above their MSR compared to 28 percent (92 of 333) in PY14 and 26 percent (58 of 220) in PY13.[54]

For Pioneer ACOs, the financial and quality results continue to be positive, with several Pioneer ACOs generating greater savings in the model performance year 4 (PY4) (2015) and one ACO generating savings for the first time. While the cohort of Pioneer ACOs decreased between PY3 (2014) and PY4, they still generated total model savings of over $37 million. It is important to note that going into PY4, the benchmarks for the Pioneer ACOs were re-based, and the Model as a whole introduced new financial benchmarking methodologies. Re-basing refers to using a newer set of baseline years to compute financial benchmarks; the new benchmarks are therefore based on ACOs' spending during their initial years of participation in the Pioneer ACO Model.[55]

Quality performance improved considerably from PY3 to PY4 and across all 4 years of the Pioneer ACO Model. Overall quality scores for nine of the 12 Pioneer ACOs were above 90 percent in PY4. All 12 Pioneers improved their quality scores from PY1 (2012) to PY4 by over 21 percentage points. The financial results were that the 12 Pioneer ACOs participating in PY4 were accountable for 461,442 beneficiaries, representing a nearly 24 percent increase in average aligned beneficiaries per ACO (up to 38,454) from PY3. PY4 was the first option year in the Pioneer ACO Model, where Pioneer ACOs were operating under a new financial benchmarking methodology. While the cohort of Pioneer ACOs decreased by nearly a third between PY3 and PY4 with several Pioneer ACOs transitioning to either the Shared Savings Program or the Next Generation ACO model Pioneer ACOs still generated total model savings (inclusive of all Pioneer ACO savings and losses relative to financial benchmarks) of over $37 million. Of the eight Pioneer ACOs that generated savings, six generated savings outside a minimum savings rate and earned shared savings, and of the four Pioneer ACOs that generated losses, one generated losses outside a minimum loss rate and owed shared losses.[56]

The results from the third program year (January through December 2015) of the original CPC Initiative indicate that the from 2013 to 2015 CPC practices transformed their care delivery —with the biggest improvements in risk-stratified care management, expanded access to care, and continuity of care. The CPC also improved patient experience slightly. Over the first 3 years, ED visits increased by 2 percent less for Medicare FFS beneficiaries in CPC practices relative to those in comparison practices.[57] [58]

As the early findings from the original CPC initiative and literature from other medical home models supported by payment suggest, we expect to see improvement in quality and patient experience of care.[59] [60] [61] [62] Under CPC+, a higher proportion of the practice revenue is de-linked from FFS payment and there is thus more flexibility for practices to deliver care without a face-to-face encounter and instead in the modality that best meets patients' health care needs (that is, office visit, virtual visit, phone call, etc.).[63] We anticipate that CPC+ will allow practices to get off the ''FFS Treadmill'' [64] and achieve incentive neutrality (the incentive to bring a patient to the office is balanced with the incentive to provide the needed care outside of an office visit).[65] [66]

While maintaining coverage of Original Medicare services and beneficiary freedom to choose providers, ACOs could potentially enhance care management of the chronically ill aligned population through the adoption of leading-edge technologies, care coordination techniques, and evidence-based benefit enhancements that motivate providers and beneficiaries to optimize care. The evidence discussed here focuses on the Next Generation Model elements of telehealth, home health care, and reduced cost sharing.

The transition from the inpatient setting to home is a critical period for patients, particularly elderly populations. Studies have examined a variety of interventions to help smooth care transitions. Interventions found in the literature include advance practice nurse-led comprehensive discharge planning and home visit follow-up protocols [67] [68] [69] and patient coaching

[52] ???

[53] CMS, ''Medicare Accountable Care Organizations 2015 Performance Year Quality and Financial Results.'' Available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html*.

[54] CMS, Medicare Accountable Care Organizations 2015 Performance Year Quality and Financial Results, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html* (last accessed April 14, 2016).

[55] *Id.*

[56] *Id.*

[57] Peikes, D., Taylor, E., Dale, S., et al. ''Evaluation of the Comprehensive Primary Care Initiative: Second Annual Report.'' Princeton, NJ: Mathematica Policy Research, April 13, 2016, available at *https://innovation.cms.gov/files/reports/cpci-evalrpt2.pdf*.

[58] For more detail see Peikes, D., Anglin, G., Taylor, E., et al. ''Evaluation of the Comprehensive Primary Care Initiative: Third Annual Report.'' Princeton, NJ: Mathematica Policy Research, December 2016, available at *https://innovation.cms.gov/Files/reports/cpci-evalrpt3.pdf*.

[59] Reid, R.J., Fishman, P.A., Yu, O., Ross, T.R., Tufano, J.T., Soman, M.P, & Larson, E.B. (2009). Patient-centered medical home demonstration: A prospective, quasi-experimental, before and after evaluation. *AJMC, 15*(9), e71–e87.

[60] Maeng, D.D., Graham, J., Graf, T.R., Liberman, J.N., Dermes, N.B., Tomcavage, J., et al. (2012). Reducing long-term cost by transforming primary care: Evidence from Geisinger's Medical Home Model. *AJMC, 18*(3), 149–155.

[61] Nelson, K.M., Helfrich, C., Sun, H., Hebert, P.L., Liu, C.F., Dolan, E., et al. (2014). Implementation of the patient-centered medical home in the Veterans Health Administration: Associations with patient satisfaction, quality of care, staff burnout, and hospital and emergency department use. *JAMA Intern Med, 174*(8), 1350–1358.

[62] DeVries, A., Li, C.H.W., Sridhar, G., Hummel, J.R., Breidbart, S., & Barron, J.J. (2012). Impact of medical homes on quality, Healthcare utilization, and costs. *AJMC, 18*(9), 534–544.

[63] Mechanic, R.E., Santos, P., Landon, B.E., & Chernew, M.E. (2011). Medical group responses to global payment: early lessons from the 'Alternative Quality Contract' in Massachusetts. *Health Aff (Millwood), 30*(9), 1734–42.

[64] Bitton, A., Schwartz, G.R., Stewart, E.E., Henderson, D.E., Keohane, C.A., Bates, D.W., & Schiff, G.D. (2012). Off the hamster wheel? Qualitative evaluation of a payment-linked patient-centered medical home (PCMH) pilot. *Milbank Q, 90*(3), 484–515.

[65] Ash, A.S., & Ellis, R.P. (2012). Risk-adjusted payment and performance assessment for primary care. *Med Care, 50*(8), 643–53.

[66] Vats, S., Ash, A.S., & Ellis, R.P. (2013). Bending the cost curve? Results from a comprehensive primary care payment pilot. *Med Care, 51*(11), 964–9.

[67] Naylor MD, Brooten D, Campbell R, et al. Comprehensive Discharge Planning and Home Follow-up of Hospitalized Elders: A Randomized Clinical Trial. JAMA. 1999;281(7):613–620.

[68] Naylor, M. D., Brooten, D. A., Campbell, R. L., Maislin, G., McCauley, K. M. and Schwartz, J. S. (2004), Transitional Care of Older Adults

accompanied by post-discharge home visits.[70] While the intensity and content of these interventions vary, the use of a post-discharge home visit shortly after leaving the hospital appears to be effective in engaging and monitoring patients to decrease readmissions or emergency room visits. MedPAC has also noted that there may be a role for home health services in models that focus on chronic care needs and care coordination.[71] The Next Generation ACO Model seeks to encourage ACOs to engage in post-discharge home visits to improve ACO patient outcomes by allowing ACOs to perform and bill for types of services not currently available under Original Medicare.

The study of the potential value and efficacy of telehealth and remote patient monitoring has become more prevalent in recent years as technology has enabled greater utilization of these services.[72] Studies and case studies from health systems have shown value in using telehealth platforms for activities such as e-visits [73] [74] and remote patient monitoring,[75] as well as for higher intensity care through real-time videoconferencing,[76] particularly to enable older adults to receive care more rapidly from their homes and with minimal burden. The Next Generation Model seeks to allow ACOs flexibility in utilizing telehealth services to improve access to the most appropriate care for ACO beneficiaries.

1. Impact on Other Health Care Programs and Providers

We estimate that the Quality Payment Program Year 2 will not have a significant economic effect on eligible clinicians and groups and believe that MIPS policies, along with increasing participation in APMs over time may succeed in improving quality and reducing costs. This may in turn result in beneficial effects on both patients and some clinicians, and we intend to continue focusing on clinician-driven, patient-centered care.

We propose several policies for the Quality Payment Program Year 2 to reduce burden. These include raising the low volume threshold so that fewer clinicians in small practices are required to participate in the MIPS starting with the 2018 performance period; including bonus points for clinicians in small practices; adding a new significant hardship exception for the advancing care information performance category for MIPS eligible clinicians in small practices; implementing virtual groups; allowing MIPS eligible clinicians and groups to submit measures and activities using as many submission mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories; implementing a voluntary facility-based scoring mechanism for the 2018 performance period that aligns with the Hospital Value Based Purchasing (VBP) Program, and extending the ability of MIPS eligible clinicians and groups to use 2014 Edition CEHRT while providing bonus points for the use of the 2015 Edition of CEHRT. Additionally, for vendors, we believe the flexibility to use EHR technology certified to either the 2014 Edition or the 2015 Edition for the Quality Payment Program Year 2 is beneficial as vendors will have additional time to deploy the updated software to their customers, which are the clinicians and other providers. Clinicians will likewise have additional time to upgrade and implement the new functionalities.

In summary, the Quality Payment Program policies are designed to promote the delivery of high-value care for individuals in all practices and areas with a particular focus on clinicians in small and solo practices. We believe each of these proposals will further reduce burdens on clinicians and practices and help increase successful participation. Further, the policies throughout this proposed rule will focus the Quality Payment Program in its second year on encouraging more complete data submission and educating clinicians. The proposed policies will continue a glide path, which began in the transition year, to more robust participation and performance in future years. The proposed policy changes are reflected in the RIA estimates, which show that the risk for negative MIPS payment adjustment is minimal for MIPS eligible clinicians, including small and solo practices that meet the proposed data completeness requirements.

2. Alternatives Considered

This proposed rule contains a range of policies, including many provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies where discretion has been exercised, presents our rationale for our proposed policies and, where relevant, analyzes alternatives that we considered. Comment is sought in section II.C.8.c. of this proposed rule on policies closely related to this Regulatory Impact Analysis, including the performance threshold. We view the performance threshold as one of the most important factors affecting the distribution of payment adjustments under the Program, and the alternatives that we considered focus on that policy.

For example, we discuss above that we modeled the effects of the proposed rule's policies using a 15-point performance threshold and a 70-point additional performance threshold. Additionally, we assumed a minimum 90 percent participation rate in each category of eligible clinicians. We displayed the results of that modeling in Table 86 along with subsequent tables.

We tested two additional models using a performance threshold of 6 points and a performance threshold of 33 points. In both of these cases, we again modeled a 70-point additional performance threshold and a minimum 90 percent participation rate in each category of eligible clinicians in order to focus the results on the differing performance thresholds.

Under the 6-point performance threshold alternative, we estimated that we would make approximately $663.5 million in positive payment adjustments (including $500 million in exceptional performance payments), and conversely, would make approximately $163.5 million in negative payment adjustments. These results represent a roughly $10 million reduction in the aggregate positive adjustments and a roughly $10 million reduction in

Hospitalized with Heart Failure: A Randomized, Controlled Trial. Journal of the American Geriatrics Society, 52: 675–684.

[69] Stauffer BD, Fullerton C, Fleming N, et al. Effectiveness and Cost of a Transitional Care Program for Heart Failure: A Prospective Study with Concurrent Controls. Arch Intern Med. 2011;171(14):1238–1243.

[70] Voss R, Gardner R, Baier R, Butterfield K, Lehrman S, Gravenstein S. The Care Transitions Intervention: Translating From Efficacy to Effectiveness. Arch Intern Med. 2011;171(14):1232–1237.

[71] Report to the Congress: Medicare and the Health Care Delivery System. March 2013.

[72] Joseph Kvedar, Molly Joel Coye and Wendy Everett, Connected Health: A Review Of Technologies and Strategies to Improve Patient Care with Telemedicine and Telehealth, Health Affairs, 33, no.2 (2014):194–199.

[73] Patrick T. Courneya, Kevin J. Palattao and Jason M. Gallagher. HealthPartners' Online Clinic For Simple Conditions Delivers Savings Of $88 Per Episode And High Patient Approval. Health Affairs, 32, no.2 (2013):385–392.

[74] Mehrotra A, Paone S, Martich G, Albert SM, Shevchik GJ. A Comparison of Care at E-visits and Physician Office Visits for Sinusitis and Urinary Tract Infection. JAMA Intern Med. 2013;173(1):72–74.

[75] UVA Health System, Tech Firm Collaborate to Reduce Hospital Readmission Rates. VHQC News. June 2014.

[76] Shah MN, Gillespie SM, et al. High-Intensity Telemedicine-Enhanced Acute Care for Older Adults: An Innovative Healthcare Delivery Model. Journal of the American Geriatrics Society. 2003; 61(11):2000–2007.

aggregate negative payment adjustments compared to the results displayed above in Table 86. Under the 6-point performance threshold, we also estimated that slightly fewer eligible clinicians would receive negative payment adjustments than in the 15-point model described further above—approximately 3.1 percent in this alternative compared to approximately 3.9 percent in the 15-point model.

Under the 33-point performance threshold alternative, we estimated that we would make approximately $743.7 million in positive payment adjustments (including $500 million in exceptional performance payments), and conversely, would make approximately $243.7 million in negative payment adjustments. These results represent a roughly $70 million increase in aggregate positive payment adjustments and a roughly $70 million increase in aggregate negative payment adjustments compared to the results displayed above in Table 86. Additionally, under the 33-point performance threshold alternative, we estimated that approximately 9.1 percent of eligible clinicians would receive a negative payment adjustment, compared to the approximately 3.9 percent that we estimated in the 15-point model.

3. Assumptions and Limitations

We would like to note several limitations to the analyses that estimated MIPS eligible clinicians' eligibility, negative MIPS payment adjustments, and positive payment adjustments for the 2020 MIPS payment year based on the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*), the preliminary version of the file used for the predictive qualifying APM participants analysis made available on *qpp.cms.gov* on June 2, 2017 and prepared using claims for services between January 1, 2016 through August 31, 2016 and 2014 and 2015 data from legacy programs, including the PQRS, CAHPS for PQRS, and the VM.

The scoring model cannot fully reflect MIPS eligible clinicians' behavioral responses to MIPS. The scoring model assumes higher participation in MIPS quality reporting than under the PQRS. Other potential behavioral responses are not addressed in our scoring model. The scoring model assumes that quality measures submitted and the distribution of scores on those measures would be similar under Quality Payment Program Payment in the 2020 MIPS payment year as they were under the 2015 PQRS program.

The scoring model does not reflect the growth in Advanced APM participation between 2017 and 2018. After applying the other MIPS exclusions, the scoring model excluded approximately 74,920 QPs using preliminary QP data for Quality Payment Program Year 2017, significantly lower than CMS' summary level projected QP counts for Quality Payment Program Year 2018 (180,000–245,000). The methods for the summary level estimates reflect the several new APMs that we anticipate will be Advanced APMs in CY 2018, and that some eligible clinicians will join the successors of APMs already active in early 2017.

There are additional limitations to our estimates. To the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Tables 86 through 90. Due the limitations above, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

E. 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 this proposed rule, we assume that the total number of 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 rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any public comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the proposed rule. We are seeking public 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 proposed rule is $105.16 per hour, including overhead and fringe benefits, which we assume are 100 percent of the hourly wage (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it would take approximately 11.5 hours for the staff to review half of this proposed rule. For each commenter that reviews this proposed rule, the estimated cost is $1209.34 (11.5 hours × $105.16). Therefore, we estimate that the total cost of reviewing this proposed rule is $4,873,360 ($1209.34 × 4,000 reviewers). We estimate that the incremental costs of reviewing this proposed rule are the same as the CY 2017 Quality Payment Program final rule.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 90 (Accounting Statement), we have prepared an accounting statement.

We have not attempted to quantify the benefits of this proposed rule because of the many uncertainties as to both clinician behaviors and resulting effects on patient health and cost reductions. For example, the applicable percentage for MIPS payment adjustments changes over time, increasing from 4 percent in 2019 to 9 percent in 2022 and subsequent years, and we are unable to estimate precisely how physicians will respond to the increasing payment adjustments. As noted above, in CY 2020, we estimate that we will distribute approximately $173 million in payment adjustments on a budget-neutral basis, which represents the applicable percent for 2020 required under section 1848(q)(6)(B)(i) of the Act and excludes $500 million in additional MIPS payment adjustments for exceptional performance.

Further, the addition of new Advanced APMs and growth in Advanced APM participation over time will affect the pool of MIPS eligible clinicians, and for those that are MIPS eligible clinicians, may change their relative performance. The $500 million available for exceptional performance and the 5 percent APM Incentive Payment for QPs are only available from 2019 through 2024. Beginning in 2026, Medicare PFS payment rates for services furnished by QPs will receive a higher update than for services furnished by non-QPs. However, we are unable to estimate the number of QPs in those years, as we cannot project the number or types of Advanced APMs that will be made available in those years through future CMS initiatives proposed and

implemented in those years, nor the number of QPs for those future Advanced APMs.

The percentage of the final score attributable to each performance category will change over time and we will continue to refine our scoring rules. The improvement activities category represents a new category for measuring MIPS eligible clinicians' performance. We may also propose policy changes in future years as we continue implementing MIPS and as MIPS eligible clinicians accumulate experience with the new system. Moreover, there are interactions between the MIPS and APM incentive programs and other shared savings and incentive programs that we cannot model or project. Nonetheless, even if ultimate savings and health benefits represent only low fractions of current experience, benefits are likely to be substantial in overall magnitude.

Table 90 includes our estimate for MIPS payment adjustments ($173 million), the exceptional performance payment adjustments under MIPS ($500 million), and incentive payments to QPs (using the range described in the preceding analysis, approximately $590–$800 million). However, of these three elements, only the negative MIPS payment adjustments are shown as estimated decreases.

TABLE 90—ACCOUNTING STATEMENT: TRANSFERS

Category	Transfers
CY 2020 Annualized Monetized Transfers	Estimated increase of between $1,263 and $1,473 million in payments for higher performance under MIPS and to QPs.[77]
From Whom to Whom?	Increased Federal Government payments to physicians, other practitioners and suppliers who receive payment under the Medicare Physician Fee Schedule.
CY 2020 Annualized Monetized Transfers	Estimated decrease of $173 million for lower performance under MIPS.
From Whom to Whom?	Reduced Federal Government payments to physicians, other practitioners and suppliers who receive payment under the Medicare Physician Fee Schedule.

Note: These estimates are identical under both a 7 percent and 3 percent discount rate.

Based on National Health Expenditure data,[78] total Medicare expenditures for physician and clinical services in 2015 reached $144.3 billion. Expenditures for physician and clinical services from all sources reached $634.9 billion. Table 90 shows that the aggregate negative MIPS payment adjustment for all MIPS eligible clinicians under MIPS is estimated at $173 million, which represents less than 0.2 percent of Medicare payments for physician and clinical services and less than 0.1 percent of payments for physician and clinician services from all sources. Table 90 also shows that the aggregate positive payment adjustment for MIPS eligible clinicians under MIPS is estimated at $673 million (including additional MIPS payment adjustments for exceptional performance), which represents less than 1 percent of Medicare expenditures for physician and clinician services and 0.2 percent of Medicare expenditures from all sources for physician and clinical services.

Table 91 summarizes the regulatory review costs discussed in section V.E. of this proposed rule, and the collection of information burden costs calculated in section III.N. of this proposed rule.

As noted above, we estimate the regulatory review costs of $4.8 million for this proposed rule. In Table 91, we have prepared our analysis of collection of information burden costs to be consistent with guidance in accordance with OMB's April 2017 guidance on EO13771. The Order's guidance directs agencies to measure certain costs, including costs associated with ''Medicare quality performance tracking'', using the estimates in the CY 2017 Quality Payment Program final rule as a baseline. The Order notes that regular updates to certain Medicare regulations make assessments of the incremental changes related to ''performance tracking'' included in a proposed regulation much more useful than a comparison against hypotheticals (such as a program's hypothetical discontinuation).

As shown in section III.N. of this proposed rule, we estimate that this proposed rule will result in approximately $857 million in collection of information-related burden. However, we estimate that the incremental collection of information-related burden associated with this proposed rule is an approximately $12.4 million reduction relative to the baseline burden of continuing the policies and information collections set forth in the CY 2017 Quality Program final rule into CY 2018. Our burden estimates reflect several proposed that would reduce burden, including the proposed reduction in the length of the CAHPS survey; our proposal to allow certain hospital-based clinicians to elect use facility-based measurements, thereby eliminating the need for additional quality data submission processes; and our proposal to allow MIPS eligible clinicians to form virtual groups, which would create efficiencies in data submission; and our proposal for significant hardship or other type of exception, including a new significant hardship exception for small practices for the advancing care information performance category.

TABLE 91—ADDITIONAL COSTS AND BENEFITS

Category of cost or benefits	Costs/benefits
Regulatory Review Costs	$4.8 million.
Incremental Collection of Information/Paperwork Reduction Act Burden Estimates.	−$12.4 million.

[77] A range of estimates is provided due to uncertainty about the number of Advanced APM participants that will meet the QP threshold in 2016.

[78] Physicians and Clinical Services Expenditures, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.*

TABLE 91—ADDITIONAL COSTS AND BENEFITS—Continued

Category of cost or benefits	Costs/benefits
Benefits of Expanded Advanced and MIPS APM Participation	Improvements in quality, patient experience of care, readmission rates, access to appropriate care, and total cost of care.
Benefits of MIPS	Improvements in quality, patient experience of care, and readmission rates.

Note: These estimates are identical under both a 7 percent and 3 percent discount rate. Incremental information collection costs are total information collection costs associated with this proposed rule minus costs associated with CY 2017 Quality Payment Program final rule.

Table 91 also shows the expected benefits associated with this proposed rule. We note that these expected benefits are qualitative in nature. We expect that the Quality Payment Program will result in quality improvements and improvements to the patients' experience of care as MIPS eligible clinicians respond to the incentives for high-quality care provided by the Program and implement care quality improvements in their clinical practices. While we cannot quantify these effects specifically at this time because we cannot project eligible clinicians' behavioral responses to the incentives offered under the Quality Payment Program, we nevertheless believe that changes to clinical care will result in care quality improvements for Medicare beneficiaries and other patients treated by eligible clinicians.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, 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 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 2. Section 414.1305 is amended by—
■ a. Removing the definition of ''Advanced APM Entity'';
■ b. Revising the definition of ''Affiliated practitioner'';
■ c. Adding the definitions of ''All-Payer QP Performance Period'' and ''Ambulatory Surgical Center (ASC)-based MIPS eligible clinician'';
■ d. Revising the definitions of ''APM Entity'' and ''Attributed beneficiary'';
■ e. Amending the definition ''Certified Electronic Health Record Technology (CEHRT)'' by revising paragraphs (1) introductory text, (1)(iii), and (2) introductory text;
■ f. Adding the definition of ''CMS Multi-Payer Model'';
■ g. Revising the definition of ''Final Score'';
■ h. Adding the definitions of ''Full TIN APM'';
■ i. Revising the definition of ''Hospital-based MIPS eligible clinician'';
■ j. Adding the definitions of ''Improvement scoring'';
■ k. Revising the definitions of ''Low-volume threshold'', and ''Medicaid APM'';
■ l. Adding the definitions of ''Medicare QP Performance Period'';
■ m. Revising the definition of ''Non-patient facing MIPS eligible clinician'';
■ n. Adding the definition or ''Other MIPS APM'';
■ o. Revising the definition of ''Other Payer Advanced APM'';
■ p. Removing the definition of ''QP Performance Period'';
■ q. Revising the definition of ''Rural areas''; and
■ r. Adding the definitions of ''Virtual group''.

The revisions and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Affiliated practitioner means an eligible clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the APM Entity for the purposes of supporting the APM Entity's quality or cost goals under the Advanced APM.

All-Payer QP Performance Period means the time period that CMS will use to assess the level of participation by an eligible clinician in Advanced APMs and Other Payer Advanced APMs under the All-Payer Combination Option for purposes of making a QP determination for the year as specified in § 414.1440. The All-Payer QP Performance Period begins on January 1 and ends on June 30 of the calendar year that is 2 years prior to the payment year.

* * * * *

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS.

* * * * *

APM Entity means an entity that participates in an APM or other payer arrangement through a direct agreement with CMS or the payer or through Federal or State law or regulation.

* * * * *

Attributed beneficiary means a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(1) For any calendar year before 2019, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

* * * * *

(iii) The definition for 2019 and subsequent years specified in paragraph (2) of this definition.

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria—

* * * * *

CMS Multi-Payer Model means an Advanced APM that CMS determines, per the terms of the Advanced APM, has at least one other payer arrangement that is designed to align with the terms of that Advanced APM.

* * * * *

Final score means a composite assessment (using a scoring scale of 0 to 100) for each MIPS eligible clinician for a performance period determined using the methodology for assessing the total

performance of a MIPS eligible clinician according to performance standards for applicable measures and activities for each performance category.

* * * * *

Full TIN APM means an APM where participation is determined at the TIN level, and all eligible clinicians who have assigned their billing rights to a participating TIN are therefore participating in the APM.

* * * * *

Hospital-based MIPS eligible clinician means a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS.

* * * * *

Improvement scoring means an assessment measuring improvement for each MIPS eligible clinician or group for a performance period using a methodology that compares improvement from one performance period to another performance period.

* * * * *

Low-volume threshold means an individual MIPS eligible clinician or group who, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries.

* * * * *

Medicaid APM means a payment arrangement authorized by a State Medicaid program that meets the Other Payer Advanced APM criteria set forth in § 414.1420.

* * * * *

Medicare QP Performance Period means the time period that CMS will use to assess the level of participation by an eligible clinician in Advanced APMs under the Medicare Option for purposes of making a QP determination for the year as specified in § 414.1425. The Medicare QP Performance Period begins on January 1 and ends on August 31 of the calendar year that is 2 years prior to the payment year.

* * * * *

Non-patient facing MIPS eligible clinician means an individual MIPS eligible clinician who bills 100 or fewer patient-facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the non-patient facing determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or within a virtual group, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period.

* * * * *

Other MIPS APM means a MIPS APM that does not require reporting through the CMS Web Interface.

Other Payer Advanced APM means an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in § 414.1420.

* * * * *

Rural areas means ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available.

* * * * *

Virtual group means a combination of two or more TINs composed of a solo practitioner (a MIPS eligible clinician (as defined at § 414.1305) who bills under a TIN with no other NPIs billing under such TIN) or a group (as defined at § 414.1305) with 10 or fewer eligible clinicians under the TIN that elects to form a virtual group with at least one other such solo practitioner or group for a performance period of a year.

■ 3. Section 414.1315 is added to read as follows:

§ 414.1315 Virtual Groups.

(a) *Eligibility.* A solo practitioner or a group of 10 or fewer eligible clinicians must make their election prior to the start of the applicable performance period and cannot change their election during the performance period. Virtual group participants may elect to be in no more than one virtual group for a performance period and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(b) *Election Deadline.* A virtual group representative must make an election, on behalf of the members of a virtual group, regarding the formation of a virtual group for an applicable performance period, by December 1 of the calendar year preceding the applicable performance year.

(c) *Election Process.* The two-stage virtual group election process for the 2018 and 2019 performance years is as follows:

(1) *Stage 1: Virtual group eligibility determination.*

(i) Solo practitioners and groups with 10 or fewer eligible clinicians interested in forming or joining a virtual group have the option to contact their designated technical assistance representative or the Quality Payment Program Service Center, as applicable, in order to obtain information pertaining to virtual groups and/or determine whether or not they are eligible, as it relates to the practice size requirement of a solo practitioner or a group of 10 or fewer eligible clinicians, to participate in MIPS as a virtual group.

(ii) [Reserved]

(2) *Stage 2: Virtual group formation.*

(i) TINs comprising a virtual group must establish a written formal agreement between each member of a virtual group prior to an election.

(ii) On behalf of a virtual group, the official designated virtual group representative must submit an election by December 1 of the calendar year prior to the start of the applicable performance period.

(iii) The submission of a virtual group election must include, at a minimum, information pertaining to each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iv) Once an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period one time prior to the start of an applicable submission period.

(3) *Agreement.* Virtual groups must execute a written formal and contractual agreement between each member of a virtual group that includes the following elements:

(i) Expressly state the only parties to the agreement are the TINs and NPIs of the virtual group.

(ii) Be executed on behalf of the TINs and the NPIs by individuals who are authorized to bind the TINs and the NPIs, respectively.

(iii) Expressly require each member of the virtual group (including each NPI under each TIN) to agree to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws and regulations (including, but not limited to, federal criminal law, False Claims Act, anti-kickback statute, civil monetary penalties law, Health Insurance Portability and Accountability Act, and physician self-referral law).

(iv) Require each TIN within a virtual group to notify all NPIs associated with the TIN regarding their participation in the MIPS as a virtual group.

(v) Set forth the NPI's rights and obligations in, and representation by, the virtual group, including without limitation, the reporting requirements and how participation in the MIPS as a virtual group affects the ability of the

NPI to participate in the MIPS outside of the virtual group.

(vi) Describe how the opportunity to receive payment adjustments will encourage each member of the virtual group (including each NPI under each TIN) to adhere to quality assurance and improvement.

(vii) Require each member of the virtual group to update its Medicare enrollment information, including the addition and deletion of NPIs billing through a TIN that is part of a virtual group, on a timely basis in accordance with Medicare program requirements and to notify the virtual group of any such changes within 30 days after the change.

(viii) Be for a term of at least one performance period as specified in the formal written agreement.

(ix) Require completion of a close-out process upon termination or expiration of the agreement that requires the TIN (group part of the virtual group) or NPI (solo practitioner part of the virtual group) to furnish all data necessary in order for the virtual group to aggregate its data across the virtual group.

(d) *Virtual Group Reporting Requirements:* For TINs participating in MIPS at the virtual group level—

(1) Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level would have their performance assessed as a virtual group.

(2) Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level would need to meet the definition of a virtual group at all times during the performance period for the MIPS payment year.

(3) Individual eligible clinicians and individual MIPS eligible clinicians who are part of a TIN participating in MIPS at the virtual group level must aggregate their performance data across multiple TINs in order for their performance to be assessed as a virtual group.

(4) MIPS eligible clinicians that elect to participate in MIPS at the virtual group level would have their performance assessed at the virtual group level across all four MIPS performance categories.

(5) Virtual groups would need to adhere to an election process established and required by CMS.

■ 4. Section 414.1320 is amended by adding paragraphs (c) and (d) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(c) For purposes of the 2021 MIPS payment year and future years, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) [Reserved]

(d) For purposes of the 2021 MIPS payment year, the performance period for:

(1) The advancing care information and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(2) [Reserved]

■ 5. Section 414.1325 is amended by revising paragraphs (c)(6) and (d) to read as follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(6) A CMS-approved survey vendor for groups that elect to include the CAHPS for MIPS survey as a quality measure. Groups that elect to include the CAHPS for MIPS survey as a quality measure must select from the above data submission mechanisms to submit their other quality information.

(d) *Report measures and activities, as applicable, via as many submission mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories.* MIPS eligible clinicians and groups may elect to submit measures and activities, as available and applicable via multiple mechanisms; however, they must use the same identifier for all performance categories.

* * * * *

■ 6. Section 414.1330 is amended by revising paragraph (b)(2) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(2) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

* * * * *

■ 7. Section 414.1335 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(2) * * *

(i) Criteria applicable to groups of 25 or more eligible clinicians, report on all measures included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module.

* * * * *

■ 8. Section 414.1340 is amended by revising paragraphs (a)(2) and (b)(2) and adding paragraphs (a)(3) and (b)(3) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(2) At least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the MIPS payment year 2020.

(3) At least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021.

(b) * * *

(2) At least 50 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2020.

(3) At least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2021.

* * * * *

■ 9. Section 414.1350 is amended by revising paragraph (b)(2) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(b) * * *

(2) 0 percent of a MIPS eligible clinicians' final score for MIPS payment year 2020.

* * * * *

■ 10. Section 414.1360 is amended by revising paragraph (a) introductory text to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years MIPS eligible clinicians must submit data on MIPS improvement activities in one of the following manners:

* * * * *

■ 11. Section 414.1370 is amended by—

■ a. Revising paragraphs (b)(4)(i); (e) and (f);

■ b. Adding paragraphs (g)(1)(i)(A) through (D), and (g)(1)(ii);

■ c. Revising paragraphs (g)(2), (g)(3)(i), (g)(4)(i) and (ii) introductory text, (h) introductory text, (h)(1), (h)(3), (h)(4); and

■ d. Adding paragraph (h)(5).

The revisions and additions read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(b) * * *

(4) * * *

(i) *New APMs.* An APM for which the first performance year begins after the first day of the APM scoring standard performance period for the year.

* * * * *

(e) *APM Entity group determination.* Except as provided in paragraph (e)(1) of this section, the APM Entity group is determined in the manner prescribed in § 414.1425(b)(1).

(1) *Full TIN APM.* The APM Entity group includes an eligible clinician who is on a Participation List in a Full TIN APM on December 31 of the APM scoring standard performance period.

(2) [Reserved]

(f) *APM Entity group scoring under the APM scoring standard.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) If a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under § 425.508 of this chapter, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard.

(2) *Virtual groups.* MIPS eligible clinicians who have elected to participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their APM Entity score.

(g) * * *

(1) * * *

(i) * * *

(A) *Quality Performance Category Score.* The MIPS Quality Performance category score for an APM scoring standard performance period is calculated for the APM Entity using the data submitted by the APM Entity through the CMS Web Interface according to the terms of the MIPS APM, including data on measures submitted through the CMS Web Interface and other measures specified by CMS for the APM scoring standard.

(B) *Quality Improvement Score.* Beginning in 2018, for an APM Entity for which we calculated a Total Quality Performance category score for the previous APM scoring standard performance period, CMS calculates a Quality Improvement Score for the APM Entity group as specified in § 414.1380(b)(1)(xvi).

(C) *Total Quality Performance Category Score.* Beginning in 2018, the Total Quality Performance category score is the sum of the Quality Performance Category Score and the Quality Improvement Score.

(D) If a Shared Savings Program ACO does not report on quality measures on behalf of its participating eligible clinicians as required by the Shared Savings Program under § 425.508 of this chapter, the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

(ii) *Other MIPS APMs.*

(A) *Quality Performance Category Score.* The MIPS Quality Performance category score for an APM scoring standard performance period is calculated for the APM Entity using the data submitted by the APM Entity based on measures that we specify through notice and comment rulemaking for each MIPS APM from among those used under the terms of the MIPS APM, and that are:

(*1*) Tied to payment;

(*2*) Available for scoring;

(*3*) Have a minimum of 20 cases available for reporting; and

(*4*) Have an available benchmark.

(B) *Quality Improvement Score.* Beginning in 2019, for an APM Entity for which we calculated a Total Quality Performance category score for the previous APM scoring standard performance period, CMS calculates a Quality Improvement Score for the APM Entity group, as specified in § 414.1380(b)(1)(xvi).

(C) *Total Quality Performance Category Score.* Beginning in 2018, the Total Quality Performance category score is the sum of the Quality Performance category score and the Quality Improvement Score.

(2) *Cost.* The cost performance category weight is zero percent for APM Entities in MIPS APMs.

(3) * * *

(i) CMS assigns an improvement activities score for each MIPS APM for an APM scoring standard performance period based on the requirements of the MIPS APM. The assigned improvement activities score applies to each APM Entity group for the APM scoring standard performance period. In the event that the assigned score does not represent the maximum improvement activities score, an APM Entity may report additional activities.

* * * * *

(4) * * *

(i) Each Shared Savings Program ACO participant TIN must report data on the Advancing Care Information (ACI) Performance category separately from the ACO, as specified in § 414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI Performance category.

(ii) For APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the ACI Performance category. The score for each MIPS eligible clinician is the higher of either:

* * * * *

(h) *APM scoring standard performance category weights.* The performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are:

(1) *Quality.*

(i) For MIPS APMs that require use of the CMS Web Interface: 50 percent.

(ii) For Other MIPS APMs, 0 percent for 2017, 50 percent beginning in 2018.

* * * * *

(3) *Improvement activities.*

(i) For MIPS APMs that require use of the CMS Web Interface: 20 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 20 percent beginning in 2018.

(4) *Advancing care information.*

(i) For MIPS APMs that require use of the CMS Web Interface: 30 percent.

(ii) For Other MIPS APMs, 25 percent for 2017, 30 percent beginning in 2018.

(5) *Reweighting the MIPS Performance categories for the APM scoring standard.* If CMS determines there are not sufficient measures or activities applicable and available to MIPS eligible clinicians, CMS will assign weights as follows:

(i) If CMS reweights the Quality Performance category to 0 percent, the Improvement Activities Performance category is reweighted to 25 percent and the Advancing Care Information Performance category is reweighted to 75 percent.

(ii) If CMS reweights the Advancing Care Information Performance category to 0 percent, the Quality Performance category is reweighted to 80 percent.

■ 12. Section 414.1375 is amended by revising paragraphs (a) and (b)(2)(ii) to read as follows:

§ 414.1375 Advancing care information performance category.

* * * * *

(a) *Final score.* The advancing care information performance category comprises 25 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and each MIPS payment year thereafter, unless a different scoring weight is assigned by CMS.

(b) * * *

(2) * * *

(ii) May claim an exclusion for each measure that includes an option for an exclusion.

* * * * *

■ 13. Section 414.1380 is revised to read as follows:

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their scores on individual measures and activities, and calculated according to the final score methodology.

(1) *Measures and activities in the four performance categories are scored against performance standards.* (i) For the quality performance category, measures are scored between zero and 10 points. Performance is measured against benchmarks. Bonus points are available for both submitting specific types of measures and submitting measures using end-to-end electronic reporting. Starting with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Starting with the 2020 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is worth a certain number of points. The points for each reported activity are summed and scored against a total potential performance category score of 40 points.

(iv) For the advancing care information performance category, the performance category score is the sum of a base score, performance score, and bonus score.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category.* For the 2017 and 2018 performance periods. MIPS eligible clinicians receive three to ten measure achievement points for each scored quality measure in the quality performance category based on the MIPS eligible clinician's performance compared to measure benchmarks. A quality measure must have a measure benchmark to be scored based on performance. Quality measures that do not have a benchmark will not be scored based on performance. Instead, these measures will receive 3 points for the 2017 MIPS performance period and either 1 or 3 points for the 2018 MIPS performance period in accordance with paragraph (b)(1)(vii) of this section.

(i) Measure benchmarks are based on historical performance for the measure based on a baseline period. Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the data completeness requirement and minimum case size criteria and performance greater than zero. Benchmark data are separated into decile categories based on a percentile distribution. We will restrict the benchmarks to data from MIPS eligible clinicians and comparable APM data, including data from QPs and Partial QPs.

(ii) As an exception, if there is no comparable data from the baseline period, CMS would use information from the performance period to create measure benchmarks, as described in paragraph (b)(1)(i) of this section, which would not be published until after the performance period. For the 2017 performance period, CMS would use information from CY 2017 during which MIPS eligible clinicians may report for a minimum of any continuous 90-day period.

(A) CMS Web Interface submission uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(B) [Reserved]

(iii) Separate benchmarks are used for the following submission mechanisms:

(A) EHR submission options;

(B) QCDR and qualified registry submission options;

(C) Claims submission options;

(D) CMS Web Interface submission options;

(E) CMS-approved survey vendor for CAHPS for MIPS submission options; and

(F) Administrative claims submission options.

(iv) Minimum case requirements for quality measures are 20 cases, unless a measure is subject to an exception.

(v) As an exception, the minimum case requirements for the all-cause hospital readmission measure is 200 cases.

(vi) MIPS eligible clinicians failing to report a measure required under this category receive zero points for that measure.

(vii) Subject to paragraph (b)(1)(viii) of this section, MIPS eligible clinicians do not receive zero points if the expected measure is submitted but is unable to be scored because it does not meet the required case minimum or if the measure does not have a measure benchmark for MIPS payment years 2019 and 2020. Instead, these measures receive a score of 3 points in MIPS payment years 2019 and 2020. MIPS eligible clinicians do not receive zero points if the expected measure is submitted but is unable to be scored because it is below the data completeness requirement. Instead, these measures receive a score of 3 points in the 2019 MIPS payment year and a score of 1 point in the 2020 MIPS payment year, except if the measure is submitted by a small practice. Measures below the data completeness requirement submitted by a small practice receive a score of 3 points in the 2020 MIPS payment year.

(viii) As an exception, the administrative claims-based measures and CMS Web Interface measures will not be scored if these measures do not meet the required case minimum. For CMS Web Interface measures, we will recognize the measure was submitted but exclude the measure from being scored. For CMS Web Interface measures: Measures that do not have a measure benchmark and measures that have a measure benchmark but are redesignated as pay for reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program, CMS will recognize the measure was submitted but exclude the measure from being scored as long as the data completeness requirement is met. CMS Web Interface measures that are below the data completeness requirement will be scored and receive 0 points.

(ix) Measures submitted by MIPS eligible clinicians are scored against measure benchmarks using a percentile distribution, separated by decile categories.

(x) For each set of benchmarks, CMS calculates the decile breaks for measure performance and assigns points based on which benchmark decile range the MIPS eligible clinician's measure rate is between.

(xi) CMS assigns partial points based on the percentile distribution.

(xii) MIPS eligible clinicians are required to submit measures consistent with § 414.1335.

(A) MIPS eligible clinicians that submit measures via claims, qualified registry, EHR, or QCDR submission mechanisms, and submit more than the required number of measures are scored on the required measures with the highest measure achievement points. MIPS eligible clinicians that report a measure via more than one submission mechanism can be scored on only one submission mechanism, which will be the submission mechanism with the highest measure achievement points. Groups that submit via these submission options may also submit and be scored on CMS-approved survey vendor for CAHPS for MIPS submission mechanisms.

(B) Groups that submit measures via the CMS Web Interface may also submit and be scored on CMS-approved survey vendor for CAHPS for MIPS submission mechanisms.

(xiii) Topped out quality measures will be identified on an annual basis and may be removed from the measure set for a submission mechanism after the third consecutive year that a given measure has been identified as topped out in connection with that submission mechanism. CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year. Topped out measures that have been removed pursuant to this policy will not be available for reporting after removal.

(A) For the 2018 MIPS performance period (2020 MIPS payment year), selected topped out measures identified by CMS will receive no more than 6 measure achievement points, provided that the measure benchmarks for all submission mechanisms are identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2019 MIPS performance period (2021 MIPS payment year), a measure, except for measures in the CMS Web Interface, whose benchmark is identified as topped out for 2 or more consecutive years will receive no more than 6 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(xiv) Measure bonus points are available for measures determined to be high priority measures when two or more high priority measures are reported.

(A) Measure bonus points are not available for the first reported high priority measure which is required to be reported. To qualify for measure bonus points, each measure must be reported with sufficient case volume to meet the required case minimum, meet the required data completeness criteria, and not have a zero percent performance rate. Measure bonus points may be included in the calculation of the quality performance category percent score regardless of whether the measure is included in the calculation of the total measure achievement points.

(B) Outcome and patient experience measures receive two measure bonus points.

(C) Other high priority measures receive one measure bonus point.

(D) Measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points for the 2019 and 2020 MIPS payment years.

(E) If the same high priority measure is submitted via two or more submission mechanisms, the measure will receive high priority measure bonus points only once for the measure.

(xv) One measure bonus point is also available for each measure submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary. Bonus points cannot exceed 10 percent of the total available measure achievement points for the 2019 and 2020 MIPS payment years. If the same measure is submitted via 2 or more submission mechanisms, the measure will receive measure bonus points only once for the measure.

(xvi) Improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to performance in the year immediately prior to the current MIPS performance period based on achievement.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period.

(1) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(2) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(3) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category percent score as described in paragraph (b)(1)(xvii) of this section.

(*1*) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of eligible clinicians from the current MIPS performance period compared to the year immediately prior to the current MIPS performance period.

(*2*) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior year quality performance category achievement percent score multiplied by 10 percent.

(*3*) An improvement percent score cannot be lower than zero percentage points.

(*4*) For the 2018 MIPS performance period, if a MIPS eligible clinician has a previous year quality performance category achievement percent score less than or equal to 30 percent, then the 2018 performance will be compared to an assumed 2017 quality performance category achievement percent score of 30 percent.

(*5*) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the total available measure achievement points,

without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category percent score as described in paragraph (b)(1)(xvii) of this section.

(F) For the purpose of improvement scoring methodology, the term ''fully participate'' means the MIPS eligible clinician met all requirements in §§ 414.1330 and 414.1340.

(xvii) A MIPS eligible clinician's quality performance category percent score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(xiv) of this section and measure bonus points in paragraph (b)(1)(xv) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(xvi) of this section is added to that result. The quality performance category percent score cannot exceed 100 percentage points.

(xviii) Beginning with the 2018 MIPS performance period, measures significantly impacted by ICD–10 updates, as determined by CMS, will be assessed based only on the first 9 months of the 12-month performance period. For purposes of this paragraph, CMS will make a determination as to whether a measure is significantly impacted by ICD–10 coding changes during the performance period. CMS will publish on the CMS Web site which measures require a 9-month assessment process by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period at § 414.1325(f)(1).

(2) *Cost performance category.* A MIPS eligible clinician receives one to ten achievement points for each cost measure attributed to the MIPS eligible clinician based on the MIPS eligible clinician's performance compared to the measure benchmark.

(i) Cost measure benchmarks are based on the performance period. Cost measures must have a benchmark to be scored.

(ii) A MIPS eligible clinician must meet the minimum case volume specified by CMS to be scored on a cost measure.

(iii) A MIPS eligible clinician cost performance category percent score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (iv).

(iv) Cost improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to their performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the measure level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement is available. Sufficient data is available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data is not available, then the cost improvement score is zero.

(C) The cost improvement score is determined by comparing the number of measures with a statistically significant change (improvement or decline) in performance; a change is determined to be significant based on application of a t-test. The number of cost measures with a significant decline is subtracted from the number of cost measures with a significant improvement, with the result divided by the number of cost measures for which the MIPS eligible clinician or group was scored for two consecutive performance periods. The resulting fraction is then multiplied by the maximum improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020 MIPS payment year is zero percentage points.

(v) A cost performance category percent score is not calculated if a MIPS eligible clinician is not attributed any cost measures because the clinician or group has not met the case minimum requirements for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(3) *Improvement activities performance category.* MIPS eligible clinicians and groups receive points for improvement activities based on patient-centered medical home or comparable specialty practice participation, APM participation, and improvement activities reported by the MIPS eligible clinician in comparison to the highest potential score (40 points) for a given MIPS year. For purposes of this paragraph, ''full credit'' means that the MIPS eligible clinician or group has met the highest potential score for the improvement activities performance category.

(i) CMS assigns credit for the total possible category score for each reported improvement activity based on two weights: Medium-weighted and high-weighted activities.

(ii) Improvement activities with a high weighting receive credit for 20 points, toward the total possible category score.

(iii) Improvement activities with a medium weighting receive credit for 10 points toward the total possible category score.

(iv) A MIPS eligible clinician or group in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, receives full credit for performance on the improvement activities performance category. A practice is certified or recognized as a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from one of four accreditation organizations that are nationally recognized;

(*1*) The Accreditation Association for Ambulatory Health Care;

(*2*) The National Committee for Quality Assurance (NCQA);

(*3*) The Joint Commission; or

(*4*) The Utilization Review Accreditation Commission (URAC).

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

(D) The practice is a participant or in a control group in the CPC+ model.

(E) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

(*1*) Have a personal physician/clinician in a team-based practice.

(*2*) Have a whole-person orientation.

(*3*) Provide coordination or integrated care.

(*4*) Focus on quality and safety.

(*5*) Provide enhanced access.

(v) CMS compares the points associated with the reported activities against the highest potential category score of 40 points.

(vi) A MIPS eligible clinician or group's improvement activities category score is the sum of points for all of their reported activities, which is capped at 40 points, divided by the highest potential category score of 40 points.

(vii) Non-patient facing MIPS eligible clinicians and groups, small practices, and practices located in rural areas and geographic HPSAs receive full credit for improvement activities by selecting one high-weighted improvement activity or two medium-weighted improvement activities. Non-patient facing MIPS eligible clinicians and groups, small practices, and practices located in rural areas and geographic HPSAs receive half credit for improvement activities by selecting one medium-weighted improvement activity.

(viii) For the transition year, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty a TIN that is reporting must include at least one practice site which is a certified patient-centered medical home or comparable specialty practice.

(ix) MIPS eligible clinicians participating in APMs that are not patient-centered medical homes for a performance period shall earn a minimum score of one-half of the highest potential score for the improvement activities performance category.

(x) For the 2018 MIPS performance period and future periods, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, CMS requires that at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice.

(4) *Advancing care information performance category.* (i) A MIPS eligible clinician's advancing care information performance category score equals the sum of the base score, performance score, and any applicable bonus scores. A MIPS eligible clinician cannot earn the performance score or base score until they have fulfilled the base score. The advancing care information performance category score will not exceed 100 percentage points.

(A) A MIPS eligible clinician earns a base score by reporting the numerator (of at least one) and denominator or a yes/no statement or an exclusion; as applicable, for each required measure.

(B) A MIPS eligible clinician earns a performance score by reporting on certain measures specified by CMS. MIPS eligible clinicians may earn up to 10 or 20 percentage points as specified by CMS for each measure reported for the performance score.

(C) A MIPS eligible clinician may earn the following bonus scores:

(1) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(2) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(3) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from 2015 Edition CEHRT.

(c) *Final score calculation.* Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated per the following formula. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (advancing care information performance category score × advancing care information performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

(i) Quality performance category weight is defined under § 414.1330(b).

(ii) Cost performance category weight is defined under § 414.1350(b).

(iii) Improvement activities performance category weight is defined under § 414.1355(b).

(iv) Advancing care information performance category weight is defined under § 414.1375(a).

(2) *Reweighting the performance categories.* A scoring weight different from the weights specified in paragraph (c)(1) of this section, will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section, will be redistributed to another performance category or categories, in the following circumstances:

(i) CMS determines there are not sufficient measures and activities applicable and available to MIPS eligible clinicians pursuant to section 1848(q)(5)(F) of the Act.

(ii) CMS estimates that the proportion of eligible professionals who are meaningful EHR users is 75 percent or greater pursuant to section 1848(q)(5)(E)(ii) of the Act.

(iii) A significant hardship exception or other type of exception is granted to a MIPS eligible clinician for the advancing care information performance category pursuant to section 1848(o)(2)(D) of the Act.

(3) *Complex patient bonus.* Provided that the MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category during the applicable performance period, a complex patient bonus will be added to the final score for the 2020 MIPS payment year, as follows:

(i) For MIPS eligible clinicians and groups, the complex patient bonus is equal to the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group.

(ii) For MIPS APMs and virtual groups, the complex patient bonus is equal to the beneficiary weighted average HCC risk score for all MIPS eligible clinicians and TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively.

(iii) The complex patient bonus cannot exceed 3.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, and for groups, virtual groups, and APM Entities that consist of 15 or fewer clinicians, that participate in the program by submitting data on at least one performance category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under § 414.1370.

(e) *Scoring for Facility-Based Measurement.* MIPS eligible clinicians may elect to be scored under the quality and cost performance categories using facility-based measures under the methodology described in this paragraph.

(1) *General.* The facility-based measurement scoring standard is the

MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) and (3) of this section.

(i) For the 2018 MIPS performance period, the facility-based measures available are the measures adopted for the FY 2019 Hospital Value-Based Purchasing Program as authorized by section 1886(o) of the Act and codified in our regulations at § 412.160 through § 412.167.

(ii) For the 2020 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians electing facility-based measurement is the Total Performance Score methodology adopted for the Hospital Value-Based Purchasing Program.

(2) *Eligibility for facility-based measurement.* MIPS eligible clinicians are eligible for facility-based measurement for a MIPS payment year if they are determined facility-based as an individual clinician or as part of a group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting based on claims for a period prior to the performance period as specified by CMS.

(ii) *Facility-based group determination.* A facility-based group is a group in which 75 percent or more of its MIPS eligible clinicians meet the requirements under paragraph (e)(2)(i) of this section.

(3) *Election of facility-based measurement.* MIPS eligible clinicians that meet the criteria described under paragraph (e)(2) of this section must elect participation in facility-based measurement through attestation.

(4) *Data submission for facility-based measurement.* There are no data submission requirements for facility-based measurement other than electing the option through attestation as described in paragraph (e)(3) of this section.

(5) *Determination of applicable facility score.* A facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the clinician or group provided services to the most Medicare beneficiaries. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard.*

(i) *Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the year specified.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year specified.

(iii) *Performance Period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year specified.

(iv) *Quality.* The quality performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(5) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category percent score [for those clinicians who are not scored using facility-based measurement] for the MIPS payment year.

(v) *Cost.* The cost performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(5) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category percent score for those clinicians who are not scored using facility-based measurement for the MIPS payment year.

(A) *Other Cost Measures.* MIPS eligible clinicians who elect facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

■ 14. Section 414.1390 is amended by adding paragraphs (b) through (d) to read as follows:

§ 414.1390 Data validation and auditing.

* * * * *

(b) *Certification.* All MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted to CMS is true, accurate, and complete. Such certification must accompany the submission.

(c) *Reopening.* CMS may reopen and revise a MIPS payment determination in accordance with the rules set forth at §§ 405.980 through 405.986 of this chapter.

(d) *Record Retention.* All MIPS eligible clinicians or groups that submit data and information to CMS for purposes of MIPS must retain such data and information for a period of 10 years from the end the MIPS Performance Period.

■ 15. Section 414.1395 is revised to read as follows:

§ 414.1395 Public reporting.

(a) *Public reporting of eligible clinician and group Quality Payment Program information.* For each program year, CMS posts on Physician Compare, in an easily understandable format, information regarding the performance of eligible clinicians or groups under the Quality Payment Program.

(b) *Maintain existing public reporting standards.* With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across reporting mechanisms; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with Web site users, as determined by CMS.

(c) *First year measures.* For each program year, CMS does not publicly report any first year measure, meaning any measure in its first year of use in the quality and cost performance categories. After the first year, CMS reevaluates measures to determine when and if they are suitable for public reporting.

(d) *30-day preview period.* For each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare.

■ 16. Section 414.1400 is amended by—

■ a. Revising paragraph (a)(1) introductory text;

■ b. Adding paragraph (a)(5);

■ c. Revising paragraphs (b), (e) introductory text, (e)(3), (f) introductory text, (f)(1), (f)(2), (g), (i) and (j)(2).

The revisions and additions read as follows:

§ 414.1400 Third party data submission.

(a) * * *

(1) MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician, group or virtual group by:

* * * * *

(5) All data submitted to CMS by a third party intermediary on behalf of a

MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete. Such certification must accompany the submission.

(b) *QCDR self-nomination criteria.* For the 2018 performance period and future years of the program, QCDRs must self-nominate from September 1 of the prior year until November 1 of the prior year. Entities that desire to qualify as a QCDR for the purposes of MIPS for a given performance period will need to self-nominate for that performance period and provide all information requested by CMS at the time of self-nomination. Having qualified as a QCDR does not automatically qualify the entity to participate in subsequent MIPS performance periods. Beginning with the 2019 performance period existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the upcoming performance period. CMS may allow existing QCDRs in good standing to submit minimal or substantial changes to their previously approved self-nomination form, from the previous year, during the annual self-nomination period, for CMS review and approval without having to complete the entire QCDR self-nomination application process.

* * * * *

(e) *Identifying QCDR quality measures.* For purposes of QCDRs submitting data for the MIPS quality performance category, CMS considers the following types of quality measures to be QCDR quality measures:

* * * * *

(3) CAHPS for MIPS survey. Although the CAHPS for MIPS survey is included in the MIPS measure set, we consider the changes that need to be made to the CAHPS for MIPS survey for reporting by individual MIPS eligible clinicians (and not as a part of a group) significant enough as to treat the CAHPS for MIPS survey as a QCDR quality measure for purposes of individual MIPS eligible clinicians reporting the CAHPS for MIPS survey via a QCDR.

(f) *QCDR measure specifications criteria.* A QCDR must provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS. The QCDR must provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than November 1 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (improvement activities and advancing care information) data starting with the 2018 performance period and in future program years.

(1) For QCDR quality measures, the quality measure specifications must include the following for each measure: name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list.

(2) For MIPS quality measures, the QCDR only needs to submit the MIPS measure numbers or specialty-specific measure sets (if applicable). CMS expects that QCDRs reporting on MIPS measures, retain and use the MIPS measure specifications as they exist under the program year.

* * * * *

(g) *Qualified registry self-nomination criteria.* For the 2018 performance period and future years of the program, the qualified registry must self-nominate from September 1 of the prior year until November 1 of the prior year. Entities that desire to qualify as a qualified registry for a given performance period must self-nominate and provide all information requested by CMS at the time of self-nomination. Having qualified as a qualified registry does not automatically qualify the entity to participate in subsequent MIPS performance periods. Beginning with the 2019 performance period, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the upcoming performance period. CMS may allow existing qualified registries in good standing to submit minimal or substantive changes to their previously approved self-nomination form from the previous year, during the annual self-nomination period, for CMS review and approval without having to complete the entire qualified registry self-nomination application process.

* * * * *

(i) *CMS-approved survey vendor application criteria.* Vendors are required to undergo the CMS approval process for each year in which the survey vendor seeks to transmit survey measures data to CMS. Applicants must adhere to any deadlines specified by CMS.

(j) * * *

(2) The entity must retain all data submitted to CMS for purposes of MIPS for a minimum of 10 years from the end of the MIPS Performance Period.

* * * * *

■ 17. Section 414.1410 is amended by revising paragraph (b) to read as follows:

§ 414.1410 Advanced APM determination.

* * * * *

(b) *Advanced APM determination process.* CMS determines Advanced APMs in the following manner:

(1) CMS updates the Advanced APM list on its Web site at intervals no less than annually.

(2) CMS will include notice of whether a new APM is an Advanced APM in the first public notice of the new APM.

■ 18. Section 414.1415 is amended by revising paragraphs (c) introductory text, (c)(2) introductory text, (c)(3)(i)(A) and (c)(4) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(c) *Financial risk.* To be an Advanced APM, an APM must either meet the financial risk standard under paragraphs (c)(1) or (2) of this section and the nominal amount standard under paragraphs (c)(3) or (4) of this section or be an expanded Medical Home Model under Section 1115A(c) of the Act.

* * * * *

(2) *Medical Home Model financial risk standard.* The following standard applies only for APM Entities that are participating in Medical Home Models starting in the 2018 Medicare QP Performance Period, except for APM Entities participating in Round 1 of the Comprehensive Primary Care Plus (CPC+) Model. This standard applies for APM Entities that are owned and operated by an organization with fewer than 50 eligible clinicians whose Medicare billing rights have been reassigned to the TIN(s) of the organization(s) or any of the organization's subsidiary entities. APM Entities under this standard participate in a Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, which may include expected expenditures, does one or more of the following:

* * * * *

(3) * * *

(i) * * *

(A) For Medicare QP Performance Periods 2017, 2018, 2019, and 2020, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(4) *Medical Home Model nominal amount standard.* (i) For a Medical

Home Model to be an Advanced APM, the total annual amount that an APM Entity potentially owes CMS or foregoes must be at least the following amounts:

(A) For Medicare QP Performance Period 2017, 2.5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(B) For Medicare QP Performance Period 2018, 2 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities;

(C) For Medicare QP Performance Period 2019, 3 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(D) For Medicare QP Performance Period 2020, 4 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(E) For Medicare QP Performance Periods 2021 and later, 5 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(ii) [Reserved]

* * * * *

■ 19. Section 414.1420 is amended by revising the section heading and paragraphs (a) introductory text, (a)(3)(i) and (ii), (c) introductory heading, (c)(2) introductory text, (c)(3), (d) introductory text, (d)(1) introductory text, (d)(3), and (4) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

(a) *Other Payer Advanced APM criteria.* A payment arrangement with a payer other than Medicare is an Other Payer Advanced APM for an All-Payer QP Performance Period if CMS determines that the arrangement meets the following criteria during an All-Payer QP Performance Period:

* * * * *

(3) * * *

(i) Requires APM Entities to bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures as described in paragraph (d) of this section; or

(ii) Is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act as described in paragraph (d) of this section.

* * * * *

(c) *Use of quality measures.*

* * * * *

(2) At least one of the quality measures used in the payment arrangement must have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

* * *

(3) To meet the quality measure use criterion, a payment arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list.

(d) *Financial risk.* To be an Other Payer Advanced APM, a payment arrangement must meet either the financial risk standard under paragraphs (d)(1) or (2) of this section and the nominal amount standard under paragraphs (d)(3) or (4) of this section, make payment using a full capitation arrangement under paragraph (d)(6) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

(1) *Generally applicable financial risk standard.* Except for APM Entities to which paragraph (d)(2) of this section applies, to be an Other Payer Advanced APM, an APM Entity must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified period of performance do one or more of the following:

* * * * *

(3) *Generally applicable nominal amount standard.* Except for payment arrangements described in paragraph (d)(2) of this section, the total amount an APM Entity potentially owes or foregoes under a payment arrangement must be at least:

(i) 8 percent of the total revenue from the payer of providers and suppliers participating in each APM Entity in the payment arrangement if financial risk is expressly defined in terms of revenue; or

(ii) At least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

(4) *Medicaid Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model to be an Other Payer Advanced APM, the total annual amount that an APM Entity potentially owes or foregoes must be at least the following amounts:

(i) For All-Payer QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.

(ii) For All-Payer QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.

(iii) For All-Payer QP Performance Periods 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

* * * * *

■ 20. Section 414.1425 is amended by—

■ a. Revising paragraphs (a), (b), (c)(3), and (c)(4)(i) and (c)(4)(ii);

■ b. Redesignating paragraph (c)(6) as paragraph (c)(4)(iii);

■ c. Revising newly redesignated paragraph (c)(4)(iii);

■ d. Adding a new paragraph (c)(6);

■ e. Revising paragraphs (d)(1) and (2); and

■ f. Removing paragraph (d)(4).

The revisions and addition read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(a) *List used for QP determination.* (1) For Advanced APMs in which all APM Entities may include eligible clinicians on a Participation List, the Participation List is used to identify the APM Entity group for purposes of QP determinations, regardless of whether the APM Entity also has eligible clinicians on an Affiliated Practitioner List.

(2) For Advanced APMs in which APM Entities do not include eligible clinicians on a Participation List but do include eligible clinicians on an Affiliated Practitioner List, the Affiliated Practitioner List is used to identify the eligible clinicians for purposes of QP determinations.

(3) For Advanced APMs in which some APM Entities may include eligible clinicians on a Participation List and other APM Entities may only include eligible clinicians on an Affiliated Practitioner List depending on the type of APM Entity, paragraph (a)(1) of this section applies to APM Entities that may include eligible clinicians on a Participation List, and paragraph (a)(2) of this section applies to APM Entities that only include eligible clinicians on an Affiliated Practitioner List.

(b) *Group or individual determination under the Medicare Option. (1) APM Entity group determination.* Except for paragraphs (b)(2) and (3) of this section, for purposes of the QP determinations for a year, eligible clinicians are grouped and assessed through their collective participation in an APM Entity group that is in an Advanced APM. To be included in the APM Entity group for purposes of the QP determination, an eligible clinician's APM participant identifier must be present on a Participation List of an APM Entity group on one of the dates: March 31, June 30, or August 31 of the Medicare QP Performance Period. An eligible clinician included on a Participation List on any one of these dates is included in the APM Entity group even if that eligible clinician is

not included on that Participation List at one of the prior or later listed dates. CMS performs QP determinations for the eligible clinicians in an APM entity group three times during the Medicare QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. An eligible clinician can only be determined to be a QP if the eligible clinician appears on the Participation List on a date (March 31, June 30, or August 31) CMS uses to determine the APM Entity group and to make QP determinations collectively for the APM Entity group based on participation in the Advanced APM.

(2) *Affiliated practitioner individual determination under the Medicare Option.* For Advanced APMs described in paragraph (a)(2) of this section, QP determinations are made individually for each eligible clinician. To be assessed as an Affiliated Practitioner, an eligible clinician must be identified on an Affiliated Practitioner List on one of the dates: March 31, June 30, or August 31 of the Medicare QP Performance Period. An eligible clinician included on an Affiliated Practitioner List on any one of these dates is assessed as an Affiliated Practitioner even if that eligible clinician is not included on the Affiliated Practitioner List at one of the prior or later listed dates. For such eligible clinicians, CMS performs QP determinations during the Medicare QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates that the eligible clinician is on the Affiliated Practitioner List: March 31, June 30, and August 31.

(3) *Individual eligible clinician determination under the All-Payer Combination Option.* Eligible clinicians are assessed under the All-Payer Combination Option as set forth in § 414.1440.

(c) * * *

(3) An eligible clinician is a QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that Medicare QP Performance Period as described in § 414.1430(a)(1) and (3). An eligible clinician is a QP for the year under the All-Payer Combination Option if the individual eligible clinician achieves a Threshold Score that meets or exceeds the corresponding QP payment amount threshold or QP patient count threshold for that All-Payer QP Performance Period as described in § 414.1430(b)(1) and (3).

(4) * * *

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the QP payment amount threshold or the QP patient count threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the QP payment amount threshold or the QP patient count threshold; unless

(iii) Any of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the Medicare QP Performance Period.

* * * * *

(6) *Advanced APMs that Start or End During the Medicare QP Performance Period.* (i) Notwithstanding paragraph (a) of this section and §§ 414.1435 and 414.1440, and except as provided in paragraph (c)(6)(ii) of this section, CMS makes QP determinations and Partial QP determinations for the APM Entity group or individual eligible clinician under § 414.1425(b) for Advanced APMs that start or end during the Medicare QP Performance Period and that are actively tested for 60 or more continuous days during the Medicare QP Performance Period using claims data for services furnished during those dates on which the Advanced APM is actively tested. For Advanced APMs that start active testing during the Medicare QP Performance Period, CMS performs QP and Partial QP determinations during the Medicare QP Performance Period using claims data for services furnished from the start of active testing of the Advanced APM through each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days: March 31, June 30, and August 31. For Advanced APMs that end active testing during the Medicare QP Performance Period, CMS performs QP and Partial QP determinations using claims data for services furnished from January 1 or the start of active testing, whichever occurs later, through the final day of active testing of the Advanced APM for each of the QP determination dates that occur on or after the Advanced APM has been actively tested for 60 or more continuous days during that Medicare QP Performance Period: March 31, June 30, and August 31.

(ii) For QP determinations specified under paragraph (c)(4) of this section and Partial QP determinations under paragraph (d)(2) of this section, QP determinations are made using claims data for the full Medicare QP Performance Period even if the eligible clinician participates in one or more Advanced APMs that start or end during the Medicare QP Performance Period.

(d) * * *

(1) An eligible clinician is a Partial QP for a year under the Medicare Option if the eligible clinician is in an APM Entity group that achieves Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that Medicare QP Performance Period as described in § 414.1430(a)(2) and (4). An eligible clinician is a Partial QP for the year under the All-Payer Combination Option if the individual eligible clinician achieves a Threshold Score that meets or exceeds the corresponding Partial QP payment amount threshold or Partial QP patient count threshold for that All-Payer QP Performance Period as described in § 414.1430(b)(2) and (4).

(2) Notwithstanding paragraph (d)(1) of this section, an eligible clinician is a Partial QP for a year if:

(i) The eligible clinician is included in more than one APM Entity group and none of the APM Entity groups in which the eligible clinician is included meets the corresponding QP or Partial QP threshold, or the eligible clinician is an Affiliated Practitioner; and

(ii) CMS determines that the eligible clinician individually achieves a Threshold Score that meets or exceeds the corresponding Partial QP Threshold; unless

(iii) Any of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the Medicare QP Performance Period.

* * * * *

■ 21. Section 414.1435 is amended by revising paragraphs (a) introductory text, (a)(1), (2), (b)(1) through (4), (c)(3), and (d) to read as follows:

§ 414.1435 Qualifying APM participant determination: Medicare option.

(a) *Payment amount method.* The Threshold Score for an APM Entity or eligible clinician is calculated as a percent by dividing the value described under paragraph (a)(1) of this section by the value described under paragraph (a)(2) of this section.

(1) *Numerator.* The aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity group to attributed beneficiaries during the Medicare QP Performance Period.

(2) *Denominator.* The aggregate of payments for Medicare Part B covered

professional services furnished by the APM Entity group to all attribution-eligible beneficiaries during the Medicare QP Performance Period.

* * * * *

(b) * * *

(1) *Numerator.* The number of attributed beneficiaries to whom the APM Entity group furnishes Medicare Part B covered professional services or is furnished services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the Medicare QP Performance Period.

(2) *Denominator.* The number of attribution-eligible beneficiaries to whom the APM Entity group or eligible clinician furnishes Medicare Part B covered professional services or is furnished services by a Rural Health Clinic (RHC) or Federally-Qualified Health Center (FQHC) during the Medicare QP Performance Period.

(3) *Unique beneficiaries.* For each APM Entity group, a unique Medicare beneficiary is counted no more than one time for the numerator and no more than one time for the denominator.

(4) *Beneficiaries count multiple times.* Based on attribution under the terms of an Advanced APM, a single Medicare beneficiary may be counted in the numerator or denominator for multiple different APM Entity groups.

(c) * * *

(3) When it is not operationally feasible to use the final attributed beneficiary list, the attributed beneficiary list will be taken from the Advanced APM's most recently available attributed beneficiary list at the end of the Medicare QP Performance Period.

(d) *Use of methods.* CMS calculates Threshold Scores for an APM Entity or eligible clinician as provided by § 414.1425(b) under both the payment amount and patient count methods for each Medicare QP Performance Period. CMS then assigns to the eligible clinicians included in the APM Entity group or to the eligible clinician the score that results in the greater QP status. QP status is greater than Partial QP status, and Partial QP status is greater than no QP status.

■ 22. Section 414.1440 is amended by revising paragraphs (a)(2), (b), (c), and (d) and adding paragraphs (e), (f), and (g) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

(a) * * *

(2) Payments and associated patient counts under paragraph (a)(1) of this section, are included in the numerator and denominator as specified in paragraphs (b)(2) and (3) of this section for an eligible clinician if CMS determines that there is at least one Medicaid APM or Medicaid Medical Home Model that is an Other Payer Advanced APM available in the county where the eligible clinician sees the most patients during the All-Payer QP Performance Period, and that the eligible clinician is eligible to participate in the Other Payer Advanced APM based on their specialty.

(b) *Payment amount method.* (1) *In general.* The Threshold Score for an eligible clinician will be calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (b)(2) and (3) of this section.

(2) *Numerator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, attributable to the eligible clinician under the terms of Advanced APMs and Other Payer Advanced APMs during the All-Payer QP Performance Period. CMS calculates Medicare Part B covered professional services under the All-Payer Combination Option at the eligible clinician level.

(3) *Denominator.* The aggregate amount of all payments from all payers, except those excluded under paragraph (a) of this section, made to the eligible clinician during the All-Payer QP Performance Period. CMS calculates Medicare Part B covered professional services under the All-Payer Combination Option at the eligible clinician level.

(c) *Patient count method.* (1) *In general.* The Threshold Score for an eligible clinician is calculated by dividing the value described under the numerator by the value described under the denominator as specified in paragraphs (c)(2) and (3) of this section.

(2) *Numerator.* The number of unique patients to whom the eligible clinician furnishes services that are included in the measures of aggregate expenditures used under the terms of all Advanced APMs and Other Payer Advanced APMs during the All-Payer QP Performance Period.

(3) *Denominator.* The number of unique patients to whom the eligible clinician furnishes services under all non-excluded payers during the All-Payer QP Performance Period.

(d) *QP Determinations under the All-Payer Combination Option.* (1) Eligible clinicians are assessed under the All-Payer Combination Option at the individual level only. CMS performs QP determinations following the All-Payer QP Performance Period using payment amount and patient count information submitted to CMS by APM Entities or eligible clinicians for January 1 through March 31 and January 1 through June 30.

(2) If the Medicare Threshold Score for an eligible clinician is higher when calculated for the APM Entity group than when calculated for the individual eligible clinician, CMS makes the QP determination under the All-Payer Combination Option using a weighted Medicare Threshold Score that will be factored into an All-Payer Combination Option Threshold Score calculated at the individual eligible clinician level.

(e) *Information used to calculate Threshold Scores under the All-Payer Combination Option.* (1) To request a QP determination under the All-Payer Combination Option, an APM Entity or eligible clinician may request that we evaluate whether a payment arrangement meets the Other Payer Advanced APM criteria as set forth in § 414.1445(b)(2) and may demonstrate participation in an Other Payer Advanced APM determined as a result of requests made in § 414.1445(a) and (b)(1) in a form and manner specified by CMS.

(2) To request a QP determination under the All-Payer Combination Option, for each payment arrangement submitted as set forth in paragraph (e)(1), the APM Entity or eligible clinician must include the amount of revenue for services furnished through the payment arrangement, the total revenue received from the all payers except those excluded as provided in paragraph (a)(2) of this section, the number of patients furnished any service through the arrangement, and the total number of patients furnished any services, except those excluded as provided in paragraph (a)(2) of this section, during the All-Payer QP Performance Period.

(f) *Requirement to submit sufficient information.* (1) CMS makes a QP determination with respect to the eligible clinician under the All-Payer Combination Option only if the APM Entity or eligible clinician submits the information required under paragraphs (e)(1) and (2) of this section sufficient for CMS to assess the eligible clinician under either the payment amount or patient count as described in paragraphs (b) and (c) of this section.

(2) *Certification.* The APM Entity or eligible clinician who submits information to request a QP determination under the All-Payer Combination Option must certify that the information submitted to CMS is true, accurate, and complete. Such certification must accompany the submission. In the case of information submitted by an APM Entity, the

certification must be made by an individual with the authority to bind the APM Entity.

(g) *Notification of QP determination.* CMS notifies eligible clinicians determined to be QPs or Partial QPs for a year as soon as practicable after QP calculations are conducted.

■ 23. Section 414.1445 is revised to read as follows:

§ 414.1445 Determination of other payer advanced APMs.

(a) *Determination of Medicaid APMs.* Beginning in 2018, at a time determined by CMS, a state, APM Entity, or eligible clinician may request, in a form and manner specified by CMS, that CMS determine whether a payer arrangement authorized under Title XIX is either a Medicaid APM or a Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria prior to the All-Payer QP Performance Period.

(b) *Determination of Other Payer Advanced APMs.* (1) *Determination prior to the All-Payer QP Performance Period.* Beginning in 2018, a payer with a Medicare Health Plan payment arrangement or a payment arrangement in a CMS Multi-Payer Model may request, in a form and manner specified by CMS, that CMS determine whether a payment arrangement meets the Other Payer Advanced APM criteria under § 414.1420 prior to the All-Payer QP Performance Period.

(2) *Determination following the All-Payer QP Performance Period.* Beginning in 2019, an APM Entity or eligible clinician may request, in a form and manner specified by CMS, that CMS determine whether a payment arrangement meets the Other Payer Advanced APM criteria under § 414.1420 following the All-Payer QP Performance Period.

(i) CMS will not determine that a payment arrangement is a Medicaid APM or a Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria after the end of the All-Payer QP Performance Period.

(ii) [Reserved]

(c) *Information Required for Determination.* (1) For a payer, APM Entity, or eligible clinician to request that CMS determine whether a payment arrangement is an Other Payer Advanced APM, Medicaid APM, or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria, a payer, APM Entity, or eligible clinician must submit payment arrangement information necessary to assess the payment arrangement on the Other Payer Advanced APM criteria under § 414.1420. If the payer, APM Entity, or eligible clinician fails to submits all of the information required under this section or does not supplement information if the need to do so as identified by CMS, then CMS will not determine whether the payment arrangement is an Other Payer Advanced APM.

(2) If an eligible clinician submits information showing that a payment arrangement requires that the eligible clinician must use CEHRT as defined in § 414.1305 to document and communicate clinical care, CMS will presume that CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(3) If a payment arrangement has no outcome measure, the payer, APM Entity, or eligible clinician submitting payment arrangement information to request a determination of whether a payment arrangement meets the Other Payer Advanced APM criteria must certify that there is no available or applicable outcome measure on the MIPS list of quality measures.

(d) *Certification.* A payer, APM Entity, or eligible clinician that submits information pursuant to paragraph (c) of this section must certify that the information it submitted to CMS is true, accurate, and complete. Such certification must accompany the submission. In case of information submitted by an APM Entity, the certification must be made by an individual with the authority to bind the APM Entity.

(e) *Timing of Other Payer Advanced APM determinations.* CMS makes Other Payer Advanced APM determinations prior to making QP determinations under § 414.1440.

(f) *Notification of Other Payer Advanced APM determinations.* CMS makes final Other Payer Advanced APM determinations and notifies the requesting payer, APM Entity, or eligible clinician of such determinations as soon as practicable following the relevant submission deadline.

■ 24. Section 414.1460 is amended by revising paragraphs (a) through (e) to read as follows:

§ 414.1460 Monitoring and program integrity.

(a) *Vetting eligible clinicians.* Prior to payment of the APM Incentive Payment, CMS determines if eligible clinicians were in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APMs in which they participated during the Medicare QP Performance Period. A determination under this provision is not binding for other purposes.

(b) *Rescinding QP Determinations.* CMS may rescind a QP determination if:

(1) Any of the information CMS relied on in making the QP determination was inaccurate or misleading.

(2) The QP is terminated from an Advanced APM or Other Payer Advanced APM during the Medicare QP Performance Period, All-Payer QP Performance Period or Incentive Payment Base Period; or

(3) The QP is found to be in violation of the terms of the relevant Advanced APM or any Federal, State, or tribal statute or regulation during the Medicare QP Performance Period, All-Payer Performance Period or Incentive Payment Base Period.

(c) *Information submitted for All-Payer Combination Option.* Information submitted by payers, APM Entities, or eligible clinicians for purposes of the All-Payer Combination Option may be subject to audit by CMS.

(d) *Reducing, Denying, and Recouping of APM Incentive Payments.*

(1) CMS may reduce or deny an APM Incentive Payment to an eligible clinician

(i) Who CMS determines is not in compliance with all Medicare conditions of participation and the terms of the relevant Advanced APM in which they participate during the Medicare QP Performance Period, All-Payer QP Performance Period, or Incentive Payment Base Period;

(ii) Who is terminated by an APM or Advanced APM during the Medicare QP Performance Period, All-Payer QP Performance Period, or Incentive Payment Base Period; or

(iii) Whose APM Entity is terminated by an APM or Advanced APM for non-compliance with any Medicare condition of participation or the terms of the relevant Advanced APM in which they participate during the Medicare QP Performance Period, All-Payer QP Performance Period, or Incentive Payment Base Period.

(2) CMS may reopen, revise, and recoup an APM Incentive Payment that was made in error in accordance with procedures similar to those set forth at §§ 405.980 through § 405.986 and §§ 405.370 through 405.379 of this chapter or as established under the relevant APM.

(e) *Maintenance of records.* (1) A payer that submits information to CMS under § 414.1445 for assessment under the All-Payer Combination Option must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination. Such information and supporting documentation must be maintained for a period of 10 years after submission.

(2) An APM Entity or eligible clinician that submits information to CMS under § 414.1445 for assessment under the All-Payer Combination Option or § 414.1440 for QP determinations must maintain such books, contracts, records, documents, and other evidence as necessary to enable the audit of an Other Payer Advanced APM determination, QP determinations, and the accuracy of APM Incentive Payments for a period of 10 years from the end of the All-Payer QP Performance Period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless:

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the APM Entity or eligible clinician at least 30 days before the formal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the APM Entity or eligible clinician, in which case the APM Entity or eligible clinician must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(3) A payer, APM Entity or eligible clinician that submits information to CMS under §§ 414.1440 or 414.1445 must provide such information and supporting documentation to CMS upon request.

* * * * *

Dated: June 7, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 13, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

Appendix

Note: For previously finalized MIPS quality measures, we refer readers to Table A in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77558). For previously finalized MIPS specialty measure sets, we refer readers to Table E in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77686). Except as otherwise proposed below, previously finalized measures and specialty measure sets would continue to apply for the Quality Payment Program year 2 and future years.

TABLE Group A: New Quality Measures Proposed for Inclusion in MIPS for the 2018 Performance Period

A.1. Average Change in Back Pain following Lumbar Discectomy / Laminotomy

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy / laminotomy procedure.
Measure Steward:	MN Community Measurement
Numerator:	This measure is not a proportion or rate, and as such, does not have a numerator and denominator, but has an eligible population with a calculated result. The calculated result is: The average change (preoperative to three months postoperative) in back pain for all eligible patients.
Denominator:	Patients 18 years of age or older as of January 1 of the measurement period who had a lumbar discectomy / laminotomy procedure for a diagnosis of disc herniation performed by an eligible provider in an eligible specialty during the measurement period and whose back pain was measured by the Visual Analog Scale (VAS) within three months preoperatively AND at three months (6 to 20 weeks) postoperatively.
Exclusions:	Patient who has had any additional spine procedures performed on the same date as the lumbar discectomy / laminotomy.
Measure Type:	Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Experience)
Data Submission Method:	Qualified Registry
Rationale:	CMS proposes to include this measure because it is outcomes focused and provides measurements related to the variations in improvement after spine surgery. This measure is useful for patients in evaluating what outcomes can be expected from surgery and clinicians who can conduct comparisons across results. The MAP has made a recommendation of conditional support, with the conditions of submission to NQF for endorsement and verification that testing supports implementation at the individual clinician level (https://www.qualityforum.org/map/)

A.2. Average Change in Back Pain following Lumbar Fusion

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery.
Measure Steward:	MN Community Measurement
Numerator:	This measure is not a proportion or rate, and as such, does not have a numerator and denominator, but has an eligible population with a calculated result. The calculated result is: The average change (preoperative to one year postoperative) in back pain for all eligible patients.
Denominator:	Patients 18 years of age or older as of January 1 of the measurement period who had a lumbar spine fusion surgery performed by an eligible provider in an eligible specialty during the measurement period and whose back pain was measured by the Visual Analog Scale (VAS) within three months preoperatively AND at one year (+/- 3 months) postoperatively.
Exclusions:	None
Measure Type:	Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Experience)
Data Submission Method:	Qualified Registry
Rationale:	CMS proposes to include this measure because it is outcomes focused and provides measurements related to the variations in improvement after spine surgery in patients. This measure is an example of quality measurement as the results can be used in evaluating whether the patient's pain was reduced as a result of the lumbar fusion. The MAP has made a recommendation of conditional support, with the conditions of submission to NQF for endorsement and verification that testing supports implementation at the individual clinician level.(https://www.qualityforum.org/map/)

A.3. Average Change in Leg Pain following Lumbar Discectomy / Laminotomy

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy / laminotomy procedure.
Measure Steward:	MN Community Measurement
Numerator:	The average change (preoperative to three months postoperative) in leg pain for all eligible patients.
Denominator:	Patients 18 years of age or older as of January 1 of the measurement period who had a lumbar discectomy and/or laminotomy procedure for a diagnosis of disc herniation performed by an eligible provider in an eligible specialty during the measurement period and whose leg pain was measured by the Visual Analog Scale (VAS) within three months preoperatively AND at three months (6 to 20 weeks) postoperatively.
Exclusions:	Patient had any additional spine procedures performed on the same date as the lumbar discectomy/ laminotomy.
Measure Type:	Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Experience)
Data Submission Method:	Qualified Registry
Rationale:	CMS proposes to include this measure because it is outcomes focused and provides measurements related to the variations in improvement after spine surgery. This measure is useful for clinicians who can conduct comparisons across results. The MAP has made a recommendation of conditional support, with the conditions of submission to NQF for endorsement and verification that testing supports implementation at the individual clinician level.(https://www.qualityforum.org/map/)

A.4. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Measure Steward:	Oregon Urology Institute
Numerator:	Patients with a bone density evaluation within the two years prior to the start of or less than three months after the start of ADT treatment.
Denominator:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Data Submission Method:	EHR
Rationale:	CMS proposes to include this measure as there are no quality measures that currently address patients with prostate cancer and a diagnosis of osteoporosis. This measure will result in better care, reduced fractures, and reduced bone density loss. The MAP has made a recommendation of conditional support, with the condition for the completion of NQF endorsement. (https://www.qualityforum.org/map/)

A.5. Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics)

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Measure Steward:	American Society of Anesthesiologists
Numerator:	Patients who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Denominator:	All patients, aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for POV.
Exclusions:	Cases in which an inhalational anesthetic is used only for induction. Organ Donors as designated by ASA Physical Status 6
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Data Submission Method:	Qualified Registry
Rationale:	CMS proposes to include this measure because it recognizes the difference in therapy required for the pediatric population with regards to the prevention of post-operative vomiting; furthermore, the American Society of Anesthesiologists have verified that testing supports the implementation of the measure at the individual clinician level. The MAP has made a recommendation of conditional support, with the conditions of submission to NQF for endorsement and verification that testing supports implementation at the individual clinician level.(https://www.qualityforum.org/map/)

A.6. Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use

Category	Description
NQF #:	657
Quality #:	To Be Determined (TBD)
Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
Numerator:	Patients who were not prescribed systemic antimicrobials.
Denominator:	All patients aged 2 months through 12 years with a diagnosis of OME.
Exclusions:	Documentation of medical reason(s) for prescribing systemic antimicrobials.
Measure Type:	Process
Measure Domain:	Patient Safety, Efficiency and Cost Reduction
High priority measure:	Yes (Appropriate Use)
Data Submission Method:	Qualified Registry
Rationale:	CMS proposes to include this measure as it promotes the practice of appropriate prescription and usage of medications in the care of all beneficiaries to facilitate health and promote well-being. The MAP has made a recommendation of support for this NQF endorsed measure. (https://www.qualityforum.org/map/)

A.7. Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	To Be Determined (TBD)
Description:	Documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.
Measure Steward:	Society of Interventional Radiology
Numerator:	Number of patients undergoing uterine artery embolization for symptomatic leiomyomas and/or adenomyosis in whom embolization endpoints are documented separately for each embolized vessel AND ovarian artery angiography or embolization performed in the presence of variant uterine artery anatomy. Embolization endpoints: Complete stasis (static contrast column for at least 5 heartbeats) / Near-stasis (not static, but contrast visible for at least 5 heartbeats) / Slowed flow (contrast visible for fewer than 5 heartbeats) / Normal velocity flow with pruning of distal vasculature / Other [specify] / Not documented Embolization strategy options for variant uterine artery anatomy: Ovarian artery angiography, Ovarian artery embolization, Abdominal Aortic angiography, None
Denominator:	All patients undergoing uterine artery embolization for symptomatic leiomyomas and/or adenomyosis.
Exclusions:	SIR Guidance: Any patients that should be excluded from reporting either in the eligible population (denominator) or from both numerator and denominator (if patient experiences outcome then exclude from denominator and numerator; if not then include in denominator). Method to risk adjust measure.
Measure Type:	Process
Measure Domain:	Patient Safety
High priority measure:	Yes (Patient Safety)
Data Submission Method:	Qualified Registry
Rationale:	The MAP has made a recommendation of refine and resubmit based on lack of test data. CMS proposes to include this measure, as field testing has been completed and there are currently no applicable uterine artery embolization technique measures in CMS quality programs. (https://www.qualityforum.org/map/)

A.8. Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life

Category	Description
NQF #:	1516
Quality #:	To Be Determined (TBD)
Description:	The percentage of children 3-6 years of age who had one or more well-child visits with a PCP during the measurement year.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Children who received at least one well-child visit with a PCP during the measurement year. The measurement year (12 month period).
Denominator:	Children 3-6 years of age during the measurement year.
Exclusions:	Numerator Exclusions: Do not include services rendered during an inpatient or ED visit. Preventive services may be rendered on visits other than well-child visits. Well-child preventive services count toward the measure, regardless of the primary intent of the visit, but services that are specific to an acute or chronic condition do not count toward the measure.
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Data Submission Method:	Qualified Registry
Rationale:	This pediatric measure fulfills an important measurement gap for pediatric patients in the 3 through 6 year olds age range; therefore, CMS is proposing its inclusion in the Pediatric specialty measure set.

A.9. Developmental Screening in the First Three Years of Life

Category	Description
NQF #:	1448
Quality #:	To Be Determined (TBD)
Description:	The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the first three years of life. This is a measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened by 12 months of age, by 24 months of age and by 36 months of age.
Measure Steward:	Oregon Health & Science University
Numerator:	The numerator identifies children who were screened for risk of developmental, behavioral and social delays using a standardized tool. National recommendations call for children to be screened at the 9, 18, and 24- OR 30-month well visits to ensure periodic screening in the first, second, and third years of life. The measure is based on three, age-specific indicators. Numerator 1: Children in Denominator 1 who had screening for risk of developmental, behavioral and social delays using a standardized screening tool that was documented by their first birthday. Numerator 2: Children in Denominator 2 who had screening for risk of developmental, behavioral and social delays using a standardized screening tool that was documented by their second birthday. Numerator 3: Children in Denominator 3 who had screening for risk of developmental, behavioral and social delays using a standardized screening tool that was documented by their third birthday. Numerator 4: Children in Denominator 4 who had screening for risk of developmental, behavioral and social delays using a standardized screening tool that was documented by their first, second or third birthday.
Denominator:	Children who meet the following eligibility requirement: Age: Children who turn 1, 2 or 3 years of age between January 1 and December 31 of the measurement year. Continuous Enrollment: Children who are enrolled continuously for 12 months prior to child's 1st, 2nd or 3rd birthday. Allowable Gap: No more than one gap in enrollment of up to 45 days during the measurement year. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the beneficiary may not have more than a 1-month gap in coverage (i.e., a beneficiary whose coverage lapses for 2 months (60 days) is not considered continuously enrolled.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Community/Population Health

Category	Description
High priority measure:	No
Data Submission Method:	Qualified Registry
Rationale:	This pediatric measure fulfills an important measurement gap related to developmental screening for pediatric patients in the 1 through 3 year olds age range; therefore, CMS is proposing its inclusion in the Pediatric specialty measure set.

TABLE Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2018 Performance Period

Note: CMS has proposed to modify the specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. Existing measures with proposed substantive changes are noted with an asterisk (*), core measures as agreed upon by Core Quality Measure Collaborative (CQMC) are noted with the symbol (§), high priority measures are noted with an exclamation point (!), and high priority measures that are appropriate use measures are noted with a double exclamation point (!!) in the column.

B.1. Allergy/Immunology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title And Description	Measure Steward
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0405	160	52v6	EHR	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis.	National Committee for Quality Assurance

B.1. Allergy/Immunology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0022	238	156v6	Registry, EHR	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.1. Allergy/Immunology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	2082	338	N/A	Registry	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
	2079	340	N/A	Registry	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.2. Anesthesiology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0236	044	N/A	Registry	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services

B.2. Anesthesiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	076	N/A	Claims, Registry	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.2. Anesthesiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
!	N/A	404	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists

B.2. Anesthesiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	2681	424	N/A	Registry	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
!	N/A	426	N/A	Registry	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists

B.2. Anesthesiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	427	N/A	Registry	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists
!	N/A	430	N/A	Registry	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	American Society of Anesthesiologists
	N/A	TBD	N/A	Registry	Process	Effective Clinical Care	**Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years of age, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.3. Cardiology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0081	005	135v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	Registry	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	145v6	Registry, EHR	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	144v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066	118	N/A	Registry	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: ACE Inhibitor or ARB Therapy--Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0068	204	164v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0018	236	165v6	Claims, Registry, EHR, Web Interface	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0022	238	156v6	Registry, EHR	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	0643	243	N/A	Registry	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
!!	N/A	322	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.	American College of Cardiology

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	323	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
!!	N/A	324	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
§	1525	326	N/A	Claims, Registry	Process	Effective Clinical Care	**Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	American College of Cardiology

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	344	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
!	N/A	345	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital.	Society for Vascular Surgeons
	N/A	373	65v7	EHR	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	Registry	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	N/A	438	347v1	Web Interface, Registry, EHR	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.3. Cardiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	441	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) • Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg • And Most recent tobacco status is Tobacco Free • And Daily Aspirin or Other Antiplatelet Unless Contraindicated And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	Registry	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance

B.3a. Electrophysiology Cardiac Specialist (Subspecialty Set of B.3 Cardiology)

Note: Each subspecialty set is effectively a separate specialty set. In instances where an Individual MIPS eligible clinician or group reports on specialty or subspecialty set, if the set has less than six measures that is all the clinician is required to report.

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	348	N/A	Registry	Outcome	Patient Safety	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	The Heart Rhythm Society
!	2474	392	N/A	Registry	Outcome	Patient Safety	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation This measure is reported as four rates stratified by age and gender: • Reporting Age Criteria 1: Females less than 65 years of age • Reporting Age Criteria 2: Males less than 65 years of age • Reporting Age Criteria 3: Females 65 years of age and older • Reporting Age Criteria 4: Males 65 years of age and older.	The Heart Rhythm Society
!	N/A	393	N/A	Registry	Outcome	Patient Safety	**HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	The Heart Rhythm Society

B.4. Gastroenterology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	0659	185	N/A	Claims, Registry	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	271	N/A	Registry	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year.	American Gastroenterologial Association

B.4. Gastroenterology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	275	N/A	Registry	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ !!	0658	320	N/A	Claims, Registry	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology
§ !	N/A	343	N/A	Registry	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American College of Gastro-enterology
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	390	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastro-enterological Association/ Physician Consortium for Performance Improvement
§	N/A	401	N/A	Registry	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Gastro-enterological Association/ Physician Consortium for Performance Improvement

B.4. Gastroenterology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	402	N/A	Registry	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Claims, Registry	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photo documentation of landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
	2152	431	N/A	Registry	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ !!	N/A	439	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastro-enterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology

B.5. Dermatology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0650	137	N/A	Registry	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
!	N/A	138	N/A	Registry	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patients visits, regardless of age, with a new occurrence of melanoma, who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
!!	0562	224	N/A	Registry	Process	Efficiency and Cost Reduction	**Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology

B.5. Dermatology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	Registry	Process	Communication and Care Coordination	**Biopsy Follow-Up**: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	337	N/A	Registry	Process	Effective Clinical Care	**Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology

B.5. Dermatology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
!	N/A	410	N/A	Registry	Outcome	Person and Caregiver Centered Experience and Outcomes	**Psoriasis: Clinical Response to Oral Systemic or Biologic Medications :** Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
	N/A	440	N/A	Registry	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days of biopsy date.	American Academy of Dermatology

B.6. Emergency Medicine

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	066	146v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	0104	107	161v6	EHR	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ !!	0058	116	N/A	Registry	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance
	N/A	187	N/A	Registry	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well.	American Heart Association

B.6. Emergency Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0651	254	N/A	Claims, Registry	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
	N/A	255	N/A	Claims, Registry	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
!!	N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery

B.6. Emergency Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery
!	N/A	415	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
!!	N/A	416	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network(PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.7. Family Medicine

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0059	001	122v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0081	005	135v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	Registry	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	145v6	Registry, EHR	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	144v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	105	009	128v6	EHR	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
!	0045	024	N/A	Claims, Registry	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Claims, Registry	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	048	N/A	Claims, Registry	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
!	N/A	050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
!!	0069	065	154v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
!!	N/A	066	146v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology - Head and Neck Surgery

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0104	107	161v6	EHR	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	109	N/A	Claims, Registry	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	125v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 -74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0034	113	130v6	Claims, Web Interface, Registry, EHR EHREHR	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ !!	0058	116	N/A	Registry	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0055	117	131v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	134v4	Registry, EHR	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	Registry	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0418	134	2v77	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0056	163	123v6	EHR	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance
!	NA	181	N/A	Claims, Registry	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0068	204	164v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0022	238	156v6	Registry, EHR	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	0643	243	N/A	Registry	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0004	305	137v6	EHR	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	124v6	EHR	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* § !	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** Summary Survey Measures may include: • Getting Timely Care, Appointments, and Information; • How well Providers Communicate; • Patient's Rating of Provider; • Access to Specialists; • Health Promotion and Education; • Shared Decision-Making; • Health Status and Functional Status; • Courteous and Helpful Office Staff; • Care Coordination; • Stewardship of Patient Resources.	Agency for Healthcare Research & Quality (AHRQ)
§	1525	326	N/A	Claims, Registry	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	American College of Cardiology
!!	N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
!!	N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
!!	N/A	334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	Registry	Process	Effective Clinical Care	**Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§!	2082	338	N/A	Registry	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
!	N/A	342	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0710	370	159v6	Web Interface, Registry, EHR	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ-9) score greater than nine who demonstrate remission at twelve months (+/- 30 days after an index visit) defined as a PHQ-9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	MN Community Measurement
	0712	371	160v6	EHR	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Patients age 18 and older with the diagnosis of major depression or dysthymia who have a Patient Health Questionnaire (PHQ-9) tool administered at least once during a 4-month period in which there was a qualifying visit.	MN Community Measurement
	N/A	373	65v7	EHR	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	377	90v7	EHR	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 65 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	1879	383	N/A	Registry	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	National Committee for Quality Assurance
	N/A	387	N/A	Registry	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1407	394	N/A	Registry	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
!	N/A	398	N/A	Registry	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	MN Community Measurement
§	N/A	400	N/A	Registry	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	N/A	401	N/A	Registry	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Gastroenterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology
	N/A	402	N/A	Registry	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	408	N/A	Registry	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
	N/A	412	N/A	Registry	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
	N/A	414	N/A	Registry	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAPPSOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0053	418	N/A	Claims, Registry	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	Registry	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	347v1	Web Interface, Registry, EHR	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	441	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) • Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg • And Most recent tobacco status is Tobacco Free • And Daily Aspirin or Other Antiplatelet Unless Contraindicated • And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	Registry	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance
§ !!	N/A	443	N/A	Registry	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ !	1799	444	N/A	Registry	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance

B.7. Family Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	N/A	447	N/A	Registry	Process	Community/ Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance
	0657	TBD	N/A	Registry	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.8. Internal Medicine

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0059	001	122v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081	005	135v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	Registry	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	145v6	Registry, EHR	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0083	008	144v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement
	0105	009	128v6	EHR	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
!	0045	024	N/A	Claims, Registry	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0046	039	N/A	Claims, Registry	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Claims, Registry	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
!	N/A	050	N/A	Claims, Registry	Process	Person and Caregiver Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology -Head and Neck Surgery
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery
§	0055	117	131v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	134v6	Registry, EHR	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0417	126	N/A	Registry	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0418	134	2v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0056	163	123v6	EHR	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance
!	N/A	181	N/A	Claims, Registry	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0068	204	164v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0022	238	156v6	EHR, Registry	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	0643	243	N/A	Registry	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0004	305	137v6	EHR	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	124v6	EHR	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* § !	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** Summary Survey Measures may include: • Getting Timely Care, Appointments, and Information; • How well Providers Communicate; • Patient's Rating of Provider; • Access to Specialists; • Health Promotion and Education; • Shared Decision-Making; • Health Status and Functional Status; • Courteous and Helpful Office Staff; • Care Coordination; • Stewardship of Patient Resources.	Agency for Healthcare Research & Quality (AHRQ)
§	1525	326	N/A	Claims, Registry	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	American College of Cardiology

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
!!	N/A	334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	Registry	Process	Effective Clinical Care	**Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§!	2082	338	N/A	Registry	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
!	N/A	342	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0710	370	159v6	Web Interface, Registry, EHR	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ-9) score greater than nine who demonstrate remission at twelve months (+/- 30 days after an index visit) defined as a PHQ-9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	MN Community Measurement
	0712	371	160v6	EHR	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Patients age 18 and older with the diagnosis of major depression or dysthymia who have a Patient Health Questionnaire (PHQ-9) tool administered at least once during a 4-month period in which there was a qualifying visit.	MN Community Measurement
	N/A	373	65v7	EHR	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	377	90v7	EHR	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 65 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	1879	383	N/A	Registry	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	National Committee for Quality Assurance
	N/A	387	N/A	Registry	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	398	N/A	Registry	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	N/A	400	N/A	Registry	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	Registry	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	American Gastro-enterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	408	N/A	Registry	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
	N/A	412	N/A	Registry	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.8. Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	414	N/A	Registry	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Claims, Registry	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	Registry	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.8 Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	N/A	438	347v1	Web Interface, Registry, EHR	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients: all considered at high risk of cardiovascular events who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical athero-sclerotic cardiovascular disease(ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
!	N/A	441	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or- None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) • Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg • And Most recent tobacco status is Tobacco Free • And Daily Aspirin or Other Antiplatelet Unless Contraindicated And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	Registry	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance

B.8 Internal Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	N/A	443	N/A	Registry	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ !	1799	444	NA	Registry	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
§	N/A	447	N/A	Registry	Process	Community / Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Claims, Registry	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
!	N/A	050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	2372	112	125v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
	0419	130	68v7	Claims, Registry, EHR,	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ !	0018	236	165v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
!	N/A	265	N/A	Registry	Process	Communication and Care Coordination	**Biopsy Follow Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
§	0032	309	124v6	EHR	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	0033	310	153v6	EHR	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	369	158v6	EHR	Process	Effective Clinical Care	**Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	OptumInsight
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	0053	418	N/A	Claims, Registry	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2063	422	N/A	Claims, Registry	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecological Society

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	428	N/A	Registry	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
	N/A	429	N/A	Claims, Registry	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	Registry	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	432	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery.	American Urogynecologic Society
!	N/A	433	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 1 month after surgery.	American Urogynecologic Society
!	N/A	434	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 1 month after surgery.	American Urogynecologic Society

B.9. Obstetrics/Gynecology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	N/A	443	N/A	Registry	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§	N/A	447	N/A	Registry	Process	Community/ Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance
§ !	0567	448	N/A	Registry	Process	Patient Safety	**Appropriate Work Up Prior to Endometrial Ablation:** Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.	Health Benchmarks-IMS Health

B.10. Ophthalmology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0086	012	143v6	Claims, Registry, EHR	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0087	014	N/A	Claims, Registry	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months.	American Academy of Ophthalmology

B.10. Ophthalmology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0088	018	167v6	EHR	Process	Effective Clinical Care	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	0089	019	142v6	Claims, Registry, EHR	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0055	117	131v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	0419	130	68v7	Claims, Registry, EHR,	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.10. Ophthalmology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0566	140	N/A	Claims, Registry	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD.	American Academy of Ophthalmology
!	0563	141	N/A	Claims, Registry	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months.	American Academy of Ophthalmology
!	0565	191	133v6	Registry, EHR	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	Physician Consortium for Performance Improvement Foundation (PCPI®
!	0564	192	132v6	Registry, EHR	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.10. Ophthalmology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	1536	303	N/A	Registry	Outcome	Person Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	N/A	384	N/A	Registry	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

B.10. Ophthalmology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	385	N/A	Registry	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
!	N/A	388	N/A	Registry	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy:** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology
!	N/A	389	N/A	Registry	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 0.5 diopters of their planned (target) refraction.	American Academy of Ophthalmology
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.11. Orthopedic Surgery

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0045	024	N/A	Claims, Registry	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxi to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0097	046	N/A	Claims, Web Interface, Registry	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
* §	0421	128	69v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record**: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0420	131	N/A	Claims, Registry	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A	178	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	179	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology
	N/A	180	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	139v6	EHR, Web Interface	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	350	N/A	Registry	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
!	N/A	351	N/A	Registry	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
!	N/A	352	N/A	Registry	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons
!	N/A	353	N/A	Registry	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American Association of Hip and Knee Surgeons

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* !	N/A	375	66v6	EHR	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Changes to the measure description: Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
!	N/A	376	56v6	EHR	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older with who received an elective primary total hip arthroplasty (THA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	408	N/A	Registry	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
	N/A	412	N/A	Registry	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.11. Orthopedic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	414	N/A	Registry	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology
	0053	418	N/A	Claims, Registry	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture	National Committee for Quality Assurance
	N/A	TBD	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy / Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy /laminotomy procedure	MN Community Measurement
	N/A	TBD	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery	MN Community Measurement
	N/A	TBD	N/A	Registry	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy / Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy / laminotomy procedure	MN Community Measurement

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
!!	0069	065	154v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode	National Committee for Quality Assurance

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology Head and Neck Surgery
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology Head and Neck Surgery
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	Registry	Process	Communication and Care Coordination	**Biopsy Follow Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology
	N/A	276	N/A	Registry	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	American Academy of Sleep Medicine

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	277	N/A	Registry	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	American Academy of Sleep Medicine
	N/A	278	N/A	Registry	Process	Effective Clinical Care	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	American Academy of Sleep Medicine
	N/A	279	N/A	Registry	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	American Academy of Sleep Medicine
	N/A	317	22v6	Registry	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
!!	N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-HIead and Neck Surgery
!!	N/A	334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery
!	N/A	357	N/A	Registry	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

B.12. Otolaryngology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	N/A	398	N/A	Registry	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	Minnesota Community Measurement
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	2152	431	N/A	Registry	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0657	TBD	N/A	Registry	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.13. Pathology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0391	099	N/A	Claims, Registry	Process	Effective Clinical Care	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	College of American Pathologists
	0392	100	N/A	Claims, Registry	Process	Effective Clinical Care	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists
	1854	249	N/A	Claims, Registry	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia	College of American Pathologists
§	1853	250	N/A	Claims, Registry	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status	College of American Pathologists
	1855	251	N/A	Claims, Registry	Structure	Effective Clinical Care	**Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists

B.13. Pathology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	395	N/A	Claims, Registry	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/ Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report	College of American Pathologists
!	N/A	396	N/A	Claims, Registry	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type	College of American Pathologists
!	N/A	397	N/A	Claims, Registry	Process	Communication and Care Coordination	**Melanoma Reporting**: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate	College of American Pathologists

B.14. Pediatrics

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0069	065	154v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
!!	N/A	066	146v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis External (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	American Academy of Otolaryngology -Head and Neck Surgery

B.14. Pediatrics (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	American Academy of Otolaryngology-Head and Neck Surgery
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0418	134	2v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
§	0405	160	52v6	EHR	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis	National Committee for Quality Assurance
§	0409	205	N/A	Registry	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection	National Committee for Quality Assurance

B.14. Pediatrics (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0024	239	155v6	EHR	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation • Percentage of patients with counseling for nutrition • Percentage of patients with counseling for physical activity	National Committee for Quality Assurance
	0038	240	117v6	EHR	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	National Committee for Quality Assurance
	0004	305	137v6	EHR	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
	0033	310	153v6	EHR	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period	National Committee for Quality Assurance

B.14. Pediatrics (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0108	366	136v7	EHR	Process	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended	National Committee for Quality Assurance
	N/A	379	74v7	EHR	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period	Centers for Medicare & Medicaid Services
!	1365	382	177v6	EHR	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.14. Pediatrics (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0576	391	N/A	Registry	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported: • The percentage of discharges for which the patient received follow-up within 30 days of discharge • The percentage of discharges for which the patient received follow-up within 7 days of discharge	National Committee for Quality Assurance
	1407	394	N/A	Registry	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday	National Committee for Quality Assurance
!	N/A	398	N/A	Registry	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools	MN Community Measurement
	N/A	402	NA	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
§ !	1799	444	N/A	Registry	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
§	N/A	447	N/A	Registry	Process	Community/ Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance

B.14. Pediatrics (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0657	TBD	N/A	Registry	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials-Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
	1516	TBD	N/A	Registry	Process	Community/Population Health	**Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life:** The percentage of children 3-6 years of age who had one or more well-child visits with a PCP during the measurement year.	National Committee for Quality Assurance
	1448	TBD	N/A	Registry	Process	Community/Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the first three years of life. This is a measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened by 12 months of age, by 24 months of age and by 36 months of age.	Oregon Health & Science University

B.15. Physical Medicine

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
!	N/A	109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.15. Physical Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0420	131	N/A	Claims, Registry	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance

B.15. Physical Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance
!	2624	182	N/A	Claims, Registry	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.15. Physical Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	N/A	408	N/A	Registry	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A	412	N/A	Registry	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A	414	N/A	Registry	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology

B.15. Physical Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2152	431	N/A	Registry	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling**: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.16. Plastic Surgery

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons

B.16. Plastic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP)	Centers for Medicare & Medicaid Services
!	N/A	355	N/A	Registry	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period	American College of Surgeons

B.16. Plastic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	356	N/A	Registry	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure	American College of Surgeons
!	N/A	357	N/A	Registry	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

B.17. Preventive Medicine

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0059	001	122v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance
!	0045	024	N/A	Claims, Registry	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication	National Committee for Quality Assurance

B.17. Preventive Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0046	039	N/A	Claims, Registry	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Claims, Registry	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	National Committee for Quality Assurance
!	N/A	109	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain	American Academy of Orthopedic Surgeons
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§	2372	112	125v6	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer	National Committee for Quality Assurance
* §	0034	113	130v66	Claims, Web Interface, Registry, EHR	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance

B.17. Preventive Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	0058	116	N/A	Registry	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance
§	0062	119	134v6	Registry, EHR	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
	0417	126	N/A	Registry	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.17. Preventive Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0418	134	2v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.17. Preventive Medicine (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	NA	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	2152	431	NA	Registry	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	347v1	Web Interface, Registry, EHR	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.18. Neurology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.18. Neurology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1814	268	N/A	Claims, Registry	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year	American Academy of Neurology

B.18.Neurology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	N/A	281	149v6	EHR	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	Registry	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12-month period	American Academy of Neurology
	N/A	283	N/A	Registry	Process	Effective Clinical Care	**Dementia: Neuro-psychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12-month period	American Academy of Neurology
!	N/A	286	N/A	Registry	Process	Patient Safety	**Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening * in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
!	N/A	288	N/A	Registry	Process	Communication and Care Coordination	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12-month period	American Academy of Neurology

B.18. Neurology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	290	N/A	Registry	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric symptoms (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) in the last 12 months	American Academy of Neurology
	N/A	291	N/A	Registry	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction in the last 12 months	American Academy of Neurology
!	N/A	293	N/A	Registry	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed in the last 12 months	American Academy of Neurology
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.18. Neurology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	N/A	386	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually	American Academy of Neurology
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	N/A	408	N/A	Registry	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A	412	N/A	Registry	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record	American Academy of Neurology
	N/A	414	N/A	Registry	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record	American Academy of Neurology

B.18. Neurology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	419	N/A	Claims, Registry	Efficiency	Efficiency and Cost Reduction	**Overuse Of Neuroimaging For Patients With Primary Headache And A Normal Neurological Examination:** Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered	American Academy of Neurology
	2152	431	N/A	Registry	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
!	N/A	435	N/A	Claims, Registry	Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved	American Academy of Neurology
	N/A	TBD	N/A	Registry	Process	Patient Safety	**Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening * in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.19. Mental/Behavioral Health

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	105	009	128v6	EHR	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks) b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months)	National Committee for Quality Assurance
	0104	107	161v6	EHR	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	2v7	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	Centers for Medicare & Medicaid Services
!	N/A	181	N/A	Claims, Registry	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder mal-treatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	N/A	281	149v6	EHR	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	Registry	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12-month period	American Academy of Neurology
	N/A	283	N/A	Registry	Process	Effective Clinical Care	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12-month period	American Academy of Neurology
!	N/A	286	N/A	Registry	Process	Patient Safety	**Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening * in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
!	N/A	288	N/A	Registry	Process	Communication and Care Coordination	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12-month period	American Academy of Neurology

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
!	N/A	325	N/A	Registry	Process	Communication/ Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition	American Psychiatric Association
	0108	366	136v7	EHR	Process	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	367	169v6	EHR	Process	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	Center for Quality Assessment and Improvement in Mental Health
§ !	0710	370	159v6	Web Interface, Registry, EHR	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** Patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire (PHQ-9) score greater than nine who demonstrate remission at twelve months (+/- 30 days after an index visit) defined as a PHQ-9 score less than five. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	MN Community Measurement
	0712	371	160v6	EHR	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Patients age 18 and older with the diagnosis of major depression or dysthymia who have a Patient Health Questionnaire (PHQ-9) tool administered at least once during a 4-month period in which there was a qualifying visit	MN Community Measurement
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	1365	382	177v5	EHR	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	1879	383	N/A	Registry	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months)	National Committee for Quality Assurance
!	0576	391	N/A	Registry	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported: • The percentage of discharges for which the patient received follow-up within 30 days of discharge • The percentage of discharges for which the patient received follow-up within 7 days of discharge	National Committee for Quality Assurance
	N/A	402	NA	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
!	0711	411	N/A	Registry	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** Adult patients age 18 years and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment. This measure additionally promotes ongoing contact between the patient and provider as patients who do not have a follow-up PHQ-9 score at six months (+/- 30 days) are also included in the denominator	MN Community Measure-ment

B.19. Mental/Behavioral Health (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	2152	431	N/A	Registry	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	TBD	N/A	Registry	Process	Patient Safety	**Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety screening in two domains of risk: dangerousness to self or others and environmental risks; and if screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.20a. Diagnostic Radiology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	145	N/A	Registry	Process	Patient Safety	**Radiology: Exposure Dose or Time Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available)	American College of Radiology
!	0508	146	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign"	American College of Radiology

B.20a. Diagnostic Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	147	N/A	Claims, Registry	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Claims, Registry	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement	American College of Radiology
	0509	225	N/A	Registry, Claims	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram	American College of Radiology
!	N/A	359	N/A	Registry	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology

B.20a. Diagnostic Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	360	N/A	Registry	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
!	N/A	361	N/A	Registry	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry that is capable of collecting at a minimum selected data elements	American College of Radiology
!	N/A	362	N/A	Registry	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	American College of Radiology

B.20a. Diagnostic Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	363	N/A	Registry	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	American College of Radiology
!!	N/A	364	N/A	Registry	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	American College of Radiology
	N/A	405	N/A	Claims, Registry	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow□up imaging recommended: • Liver lesion ≤ 0.5 cm • Cystic kidney lesion < 1.0 cm • Adrenal lesion ≤ 1.0 cm	American College of Radiology

B.20a. Diagnostic Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	406	N/A	Claims, Registry	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended	American College of Radiology
	N/A	436	N/A	Claims, Registry	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique	American College of Radiology/American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.20b. Interventional Radiology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	076	N/A	Claims, Registry	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of

B.20b. Interventional Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	145	N/A	Claims, Registry	Process	Patient Safety	**Radiology: Exposure Dose or Time Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available)	American College of Radiology
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	409	N/A	Registry	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention	Society of Interventional Radiology
	N/A	413	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours	Society of Interventional Radiology
	N/A	420‡	N/A	Registry	Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A	421	N/A	Registry	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology

B.20b. Interventional Radiology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	437	N/A	Claims, Registry	Outcome	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	Society of Interventional Radiology
	N/A	TBD	N/A	Registry	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** Documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries	Society of Interventional Radiology

B.21. Nephrology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0059	001	122v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§ !	0097	046	N/A	Claims, Web Interface, Registry	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance

B.21. Nephrology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§	0062	119	134v6	Registry, EHR	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
	N/A	122	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care	Renal Physicians Association

B.21. Nephrology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0419	130	68v7	Claims, Registry, EHR,	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	2624	182	N/A	Claims, Registry	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	Centers for Medicare & Medicaid Services
	N/A	317	22v6	Claims, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	139v6	EHR, Web Interface	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.21. Nephrology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	327	N/A	Registry	Process	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	Renal Physicians Association
!	1667	328	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association
	N/A	329	N/A	Registry	Outcome	Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated	Renal Physicians Association
	N/A	330	N/A	Registry	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter	Renal Physicians Association

B.21. Nephrology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	400	N/A	Registry	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection	Physician Consortium for Performance Improvement
	N/A	403	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of ESRD who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care	Renal Physicians Association

B.22. General Surgery

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons

B.22. General Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0097	046	N/A	Claims, Web Interface, Registry	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.22. General Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record**: Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mincral/dictary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.22. General Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	355	N/A	Registry	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period	American College of Surgeons
!	N/A	356	N/A	Registry	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure	American College of Surgeons
!	N/A	357	N/A	Registry	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop:** Receipt of Specialist Report Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance

B.23. Vascular Surgery

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.23. Vascular Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0018	236	165v6	Claims, Registry, EHR, Web Interface	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period	National Committee for Quality Assurance
	1519	257	N/A	Registry	Process	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge	Society for Vascular Surgeons

B.23. Vascular Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	258	N/A	Registry	Outcome	Patient Safety	**Rate of Open Elective Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)	Society for Vascular Surgeons
!	N/A	259	N/A	Registry	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
!	N/A	260	N/A	Registry	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2)	Society for Vascular Surgeons
	N/A	317	22v6	Claims, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.23. Vascular Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	344	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2	Society for Vascular Surgeons
!	N/A	345	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital	Society for Vascular Surgeons
!	1540	346	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital.	Socicty for Vascular Surgeons
!	1534	347	N/A	Registry	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital:** Percent of patients undergoing endovascular repair of small or moderate infrarenal abdominal aortic aneurysms (AAA) who die while in the hospital	Society for Vascular Surgeons
!	N/A	357	N/A	Registry	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	American College of Surgeons
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons

B.23. Vascular Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance
	1523	417	N/A	Registry	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate abdominal aortic aneurysms (AAA) who are discharged alive	Society for Vascular Surgeons
	N/A	420‡	N/A	Effective Clinical Care	Registry	Outcome	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey**: Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	0465	423	N/A	Registry, Claims	Process	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery	Society for Vascular Surgeons

B.23. Vascular Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	441441	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) • Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg • And Most recent tobacco status is Tobacco Free • And Daily Aspirin or Other Antiplatelet Unless Contraindicated • And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.24. Thoracic Surgery

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons

B.24. Thoracic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0134	043	N/A	Registry	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0129	164	N/A	Registry	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours	American Thoracic Society
!	0130	165	N/A	Registry	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention	American Thoracic Society

B.24. Thoracic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0131	166	N/A	Registry	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	American Thoracic Society
!	0114	167	N/A	Registry	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	American Thoracic Society
!	0115	168	N/A	Registry	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	Society of Thoracic Surgeons
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0018	236	165v6	Claims, Registry, EHR, Web Interface	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period	National Committee for Quality Assurance

B.24. Thoracic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance

B.24.Thoracic Surgery (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	441	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) • Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg • And Most recent tobacco status is Tobacco Free • And Daily Aspirin or Other Antiplatelet Unless Contraindicated And Statin Use.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
	0119	445	N/A	Registry	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure	Society of Thoracic Surgeons

B.25. Urology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	0389	102	129v7	Registry, EHR	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0390	104	N/A	Registry	Process	Effective Clinical Care	**Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist	American Urological Association Education and Research
§	0062	119	134v6	Registry, EHR	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period	National Committee for Quality Assurance
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services

B.25. Urology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Claims, Registry	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	National Committee for Quality Assurance
!	N/A	050	N/A	Claims, Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	National Committee for Quality Assurance

B.25. Urology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0420	131	N/A	Claims, Registry	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	Registry	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology

B.25. Urology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
!	N/A	358	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon	American College of Surgeons
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	428	N/A	Registry	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
	N/A	429	N/A	Claims, Registry	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	Registry	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user	Physician Consortium for Performance Improvement

B.25. Urology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	432	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery	American Urogynecologic Society
	N/A	433	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 1 month after surgery	American Urogynecologic Society
	N/A	434	N/A	Registry	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 1 month after surgery	American Urogynecologic Society
	N/A	TBD	645v1	EHR	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.26. Oncology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ !!	0389	102	129v7	Registry, EHR	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§ !	0384	143	157v6	Registry, EHR	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	Physician Consortium for Performance Improvement Foundation (PCPI®

B.26. Oncology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0383	144	N/A	Registry	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	American Society of Clinical Oncology
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	1853	250	N/A	Claims, Registry	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.26. Oncology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	402	N/A	Registry	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	Registry	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
§ !!	1857	449	N/A	Registry	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies	American Society of Clinical Oncology
§ !!	1858	450	N/A	Registry	Process	Efficiency and Cost Reduction	**Trastuzumab Received By Patients With AJCC Stage I (T1c) –III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab	American Society of Clinical Oncology
§	1859	451	N/A	Registry	Process	Effective Clinical Care	**KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy::** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed.	American Society of Clinical Oncology

B.26. Oncology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	1860	452	N/A	Registry	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal: Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ !!	0210	453	N/A	Registry	Process	Effective Clinical Care	**Proportion Receiving Chemotherapy in the Last 14 Days of life:** Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ !!	0211	454	N/A	Registry	Outcome	Effective Clinical Care	**Proportion of Patients who Died from Cancer with more than One Emergency Department Visit in the Last 30 Days of Life:** Proportion of patients who died from cancer with more than one emergency room visit in the last 30 days of life.	American Society of Clinical Oncology
§ !!	0213	455	N/A	Registry	Outcome	Effective Clinical Care	**Proportion Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life:** Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ !!	0215	456	N/A	Registry	Process	Effective Clinical Care	**Proportion Not Admitted to Hospice:** Proportion of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology
§ !!	0216	457	N/A	Registry	Outcome	Effective Clinical Care	**Proportion Admitted to Hospice for less than 3 days:** Proportion of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A	TBD	645v1	EHR	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.26a. Radiation Oncology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !!	0389	102	129v7	Registry, EHR	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ !	0384	143	157v6	Registry, EHR	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	0383	144	N/A	Registry	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	American Society of Clinical Oncology
!!	0382	156	N/A	Claims, Registry	Process	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues	American Society for Radiation Oncology

B.27. Hospitalists

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§	0081	005	135v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	144v6	Registry, EHR	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.27. Hospitalists (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	N/A	076	N/A	Claims, Registry	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed	American Society of Anesthesiologists
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!!	N/A	407‡	N/A	Claims, Registry	Process	Effective Clinical Care	**Appropriate Treatment of MSSA Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Disease Society of America

B.28. Rheumatology

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	0045	024	N/A	Claims, Registry	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication	National Committee for Quality Assurance
	0046	039	N/A	Claims, Registry	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis	National Committee for Quality Assurance
	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.28. Rheumatology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
!	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
!	0420	131	N/A	Claims, Registry	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Centers for Medicare & Medicaid Services
	N/A	176	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
	N/A	177	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	American College of Rheumatology

B.28. Rheumatology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	178	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months	American College of Rheumatology
	N/A	179	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months	American College of Rheumatology
	N/A	180	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	American College of Rheumatology
* §	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.28. Rheumatology (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
§ !	0018	236	165v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance
*	0022	238	156v6	Registry, EHR	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 6565 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* !	N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	Registry	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.29. Infectious Disease

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0069	065	154v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months--18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode	National Committee for Quality Assurance
!!	N/A	066	146v6	Registry, EHR	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
!!	0653	091	N/A	Claims, Registry	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery
!!	0654	093	N/A	Claims, Registry	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041	110	147v7	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0043	111	127v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§ !!	0058	116	N/A	Registry	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance

B.29. Infectious Disease (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	176	N/A	Registry	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
§	0409	205	N/A	Registry	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection	National Committee for Quality Assurance

B.29. Infectious Disease (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	275	N/A	Registry	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association
!!	N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery
!!	N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery

B.29. Infectious Disease (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology-Otolaryngology-Head and Neck Surgery
!!	N/A	334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology-Otolaryngology-Head and Neck Surgery
	N/A	337	N/A	Registry	Process	Effective Clinical Care	**Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ !	2082	338	N/A	Registry	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year	Health Resources and Services Administration
	2079	340	N/A	Registry	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits	Health Resources and Services Administration
	N/A	387	N/A	Registry	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12 month reporting period	Physician Consortium for Performance Improvement

B.29. Infectious Disease (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	390	N/A	Registry	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment	American Gastroenterological Association
	1407	394	N/A	Registry	Process	Community /Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday	National Committee for Quality Assurance
§	N/A	400	N/A	Registry	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	Registry	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period	American Gastro-enterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology

B.29. Infectious Disease (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	N/A	407‡	N/A	Claims, Registry	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Sensitive Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Diseases Society of America
§	N/A	447	N/A	Registry	Process	Community / Population Health	**Chlamydia Screening and Follow Up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period	National Committee for Quality Assurance
	0657	TBD	N/A	Registry	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.30. Neurosurgical

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!!	0268	021	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	American Society of Plastic Surgeons
!	0239	023	N/A	Claims, Registry	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxi to be given within 24 hours prior to incision time or within 24 hours after surgery end time	American Society of Plastic Surgeons

B.30. Neurosurgical (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	Registry	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well	American Heart Association
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.30. Neurosurgical (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
!	1543	345	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital	Society for Vascular Surgeons
!	1540	346	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital.	Society for Vascular Surgeons
	N/A	409	N/A	Registry	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention	Society of Interventional Radiology
	N/A	413	N/A	Registry	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours	Society of Interventional Radiology
	N/A	TBD	N/A	Registry	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure	MN Community Measurement
	N/A	TBD	N/A	Registry	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery	MN Community Measurement
	N/A	TBD	N/A	Registry	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure	MN Community Measurement

B.31. Podiatry

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	0417	126	N/A	Registry	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	Registry	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention-Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
!	0101	154	N/A	Claims, Registry	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	National Committee for Quality Assurance
!	0101	155	N/A	Claims, Registry	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	National Committee for Quality Assurance

B.31. Podiatry (continued)

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
*	0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.32. Dentistry

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
	N/A	378	75v6	EHR	Outcome	Community /Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period	Centers for Medicare & Medicaid Services
	N/A	379	74v7	EHR	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

TABLE C.1: Proposed MIPS Measures Removed Only from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
0059	001	122v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	National Committee for Quality Assurance	Emergency Medicine
N/A	032	N/A	Claims, Registry	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) who were prescribed an antithrombotic therapy at discharge.	American Academy of Neurology	Neurosurgical Neurology Hospitalists
0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	Emergency Medicine Mental/Behavioral Health Ophthalmology Plastic Surgery

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
0421	128	69v6	Claims, Registry, EHR, Web Interface	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services	Hospitalist Neurology Plastic Surgery
0419	130	68v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	Anesthesiology Emergency Medicine

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
0028	226	138v6	Claims, Registry, EHR, Web Interface	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	Emergency Medicine Hospitalist
0018	236	165v6	Claims, Registry, EHR, Web Interface	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period	National Committee for Quality Assurance	Preventative Medicine
N/A	259	N/A	Registry	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	Socicty for Vascular Surgeons	Interventional Radiology

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
N/A	265	N/A	Registry	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	American Academy of Dermatology	Interventional Radiology
	284	N/A	Registry	Process	Effective Clinical Care	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12-month period	American Academy of Neurology	Neurology Mental/ Behavioral Health
N/A	294	N/A	Registry	Process	Communication and Care Coordination	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	American Academy of Neurology	Neurology
N/A	304	N/A	Registry	Outcome	Person Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	American Academy of Ophthalmology	Ophthalmology

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
N/A	312	166v7	EHR	Process	Efficiency and Cost Reduction	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis	National Committee for Quality Assurance	Family Medicine Internal Medicine Orthopedic Surgery Physical Medicine
N/A	317	22v6	Claims, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services	Ophthalmology Hospitalist
N/A	331	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms	American Academy of Otolaryngology-Head and Neck Surgery	Allergy/Immunology
N/A	332	N/A	Registry	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	American Academy of Otolaryngology-Head and Neck Surgery	Allergy/Immunology

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
N/A	333	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	American Academy of Otolaryngology- Head and Neck Surgery	Allergy/Immunology
N/A	334	N/A	Registry	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overusc):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	American Academy of Otolaryngology- Head and Neck Surgery	Allergy/Immunology
N/A	337	N/A	Registry	Process	Effective Clinical Care	**Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology	Rheumatology
N/A	344	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2	Society for Vascular Surgeons	Interventional Radiology

TABLE C.1: Proposed MIPS Measures Removed from Specialty Sets for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
1543	345	N/A	Registry	Outcome	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital	Society for Vascular Surgeons	Interventional Radiology
N/A	374	50v6	Registry, EHR	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	Emergency Medicine Plastic Surgery Hospitalist
N/A	398	N/A	Registry	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation	MN Community Measure-ment	Allergy/ Immunology
N/A	402	N/A	Registry	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user	National Committee for Quality Assurance	Emergency Medicine Hospitalist Plastic Surgery Urology
2152	431	N/A	Registry	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use:** Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	Emergency Medicine Hospitalist

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Specialty Set Proposed to be Removed From
1799	444	N/A	Registry	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	Allergy/ Immunology

TABLE C.2: Proposed Quality Measures Removed from Merit-Based Incentive Payment System Program for the 2018 Performance Period

Note: CMS proposed removal of measures within specific specialty measure sets based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. Measure specific removal rationale is provided in the table below. For example, this measure has been proposed for removal because of outdated measure specifications based on current clinical guidelines.

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	032	N/A	Claims, Registry	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) who were prescribed an antithrombotic therapy at discharge.	American Academy of Neurology	CMS proposes the removal of the measure "Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy" as a quality measure from the MIPS program, due to the measure steward no longer maintaining the measure since there are similar existing measures being maintained by other measure stewards. We request comment on the removal of this measure from the Merit-Based Incentive Payment System (MIPS) program.
N/A	284	N/A	Registry	Process	Effective Clinical Care	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12-month period	American Academy of Neurology	CMS proposes the removal of the measure "Dementia: Management of Neuropsychiatric Symptoms" as a quality measure from the MIPS program, due to the measure steward no longer maintaining the measure since it was combined with Q283 Dementia: Neuro-Psychiatric Symptom Assessment. We request comment on the removal of this measure from MIPS.

TABLE C.2: Proposed Quality Measures Removed from Merit-Based Incentive Payment System Program for the 2018 Performance Period

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	294	N/A	Registry	Process	Communication and Care Coordination	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	American Academy of Neurology	CMS proposes the removal of the measure "Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed" as a quality measure from the MIPS program, due to the measure steward no longer maintaining the measure. We request comment on the removal of this measure from the Merit-Based Incentive Payment System (MIPS) program.

TABLE C.2: Proposed Quality Measures Removed from Merit-Based Incentive Payment System Program for the 2018 Performance Period

NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	312	166v7	EHR	Process	Efficiency and Cost Reduction	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis	National Committee for Quality Assurance	CMS proposes the removal of the measure "Use of Imaging Studies for Low Back Pain" as a quality measure from the MIPS program, due to the age cut off as stated in the current measure description. The American College of Radiology's current guidelines suggest that imaging be performed in adults older than 50 years of age who present with lower back pain. CMS had provided the measure steward with the opportunity to update the age range, in order to retain the measure within the program however, no changes have been made to the measure description. We request comment on the removal of this measure from the Merit-Based Incentive Payment System (MIPS) program.

TABLE D: 2018 Proposed Cross-Cutting Measures

Note: The table of cross-cutting measures is intended to provide clinicians with a list of measures that are broadly applicable to all clinicians regardless of the clinician's specialty. Even though it is not required to report on cross-cutting measures, it is provided as a reference to clinicians who are looking for additional measures to report outside their specialty.

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
!	0326	047	N/A	Claims, Registry	Process	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	69v669v6	Claims, Web Interface, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Centers for Medicare & Medicaid Services
!	0419	130	68v768v7	Claims, Registry, EHR	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

TABLE D: 2018 Proposed Cross-Cutting Measures

Note: The table of cross-cutting measures is intended to provide clinicians with a list of measures that are broadly applicable to all clinicians regardless of the clinician's specialty. Even though it is not required to report on cross-cutting measures, it is provided as a reference to clinicians who are looking for additional measures to report outside their specialty.

Indicator	NQF #	Quality #	CMS E-Measure ID	Data Submission Method	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028	226	138v6	Claims, Web Interface, Registry, EHR	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ !	0018	236	165v6	Claims, Web Interface, Registry, EHR	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance
	N/A	317	22v6	Claims, Registry, EHR	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated	Centers for Medicare & Medicaid Services

TABLE E: Measures with Substantive Changes Proposed for MIPS Reporting in 2018

E.1. CAHPS for MIPS Clinician/Group Survey

Category	Description
NQF #:	0005 & 0006
Quality#:	321
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data Submission Method:	CMS Approved Survey Vendor
Current Measure Description:	The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 12 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice.
Proposed Substantive Change:	The proposed survey would eliminate 2 SSMs (Helping You to Take Medication as Directed and Between Visit Communication)
Steward:	Agency for Healthcare Research & Quality (AHRQ)
High Priority Measure:	Yes (Patient Experience)
Rationale:	For the Quality Payment Program Year 2 and beyond, CMS proposes to remove two SSMs, "Helping You to Take Medication as Directed" due to low reliability and "Between Visit Communication" as this SSM currently contains only one question. This question could also be considered related to other SSMs entitled: "Care Coordination" or "Courteous and Helpful Office Staff," but does not directly overlap with any of the questions under that SSM. However, we are proposing to remove this SSM in order to maintain consistency with the Medicare Shared Savings Program that utilizes the CAHPS Survey for Accountable Care Organizations (ACOs). The SSM entitled "Between Visit Communication" has never been a scored measure with the Medicare Shared Savings Program CAHPS Survey for ACOs. Please refer to section II.C.6.b.(3)(a)(iii) of this proposed rule for additional details on the removal of the two SSMs.

E.2. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF #:	0028
Quality#:	226
CMS E-Measure ID:	138v6138v6
National Quality Strategy Domain:	Community/Population Health
Current Data Submission Method:	EHR, Claims, Web Interface, Qualified Registry
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.
Proposed Substantive Change:	We are proposing to restructure the measure more similarly to its original construct to make it more apparent where potential gaps in care exist and how performance can be improved. Instead of being comprised of just 1 performance rate (Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user), it is now comprised of the 3 components below: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.
Steward:	Physician Consortium for Performance Improvement (PCPI)
High Priority Measure:	No
Rationale:	This measure was originally developed as a two-part measure: the first part assessed whether a patient had been screened for tobacco use within the past 24 months; the second part assessed whether those who had been screened and identified as tobacco users in the first part of the measure also received tobacco cessation intervention (either counseling and/or pharmacotherapy). The two parts were eventually combined into one performance rate. That performance rate is collective and does not show the difference in performance with respect to how well clinicians adhere to performing tobacco use screenings and how well clinicians follow the guidelines to provide tobacco cessation interventions. As written, the measure has had a continuously high performance rate. The performance rate currently does not differentiate between smokers and non-smokers with regards to counseling, thereby demonstrating a potential inaccurately high performance rate. To address this, based on discussions with CMS' Million Hearts program as well as the technical expert panel (TEP) recently convened by our measure development contractor, the measure has been updated to more accurately reflect the intended quality action. Accordingly, the measure will look to assess tobacco use, the percentage of patients who use tobacco and were counseled to quit and the overall percentage of patients who received counseling.

E.3. Dementia: Cognitive Assessment

Category	Description
NQF #:	N/A
Quality #:	281
CMS E-Measure ID:	149v6
National Quality Strategy Domain:	Effective Clinical Care
Current Data Submission Method:	EHR
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period
Proposed Substantive Change:	The measure currently allows for medical exceptions, including diagnosis of severe dementia, palliative care, or other medical reasons, from numerator compliance.
Steward:	Physician Consortium for Performance Improvement (PCPI)
High Priority Measure:	No
Rationale:	The technical expert panel convened by our measure development contractor recommended removing these exceptions as cognitive assessment is especially important for planning the care of patients who are very sick or have advanced-stage dementia. The denominator identifies patients with dementia. Prior to this change, patients with severe dementia, palliative care, and medical reasons were removed from the denominator. While the denominator seeks patients with dementia, the number of patients with severe dementia is likely non-trivial and could impact performance rates. It is recognized that patients with perceived severe dementia still need an objective assessment of their cognition to appropriately care for them.

E.4. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF #:	0421
Quality #:	128
CMS E-Measure ID:	69v6
National Quality Strategy Domain:	Community/Population Health
Current Data Submission Method:	Claims, Web Interface, Registry, EHR
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2
Proposed Substantive Change:	Change the frequency of documenting BMI from 6 to 12 months.
Steward:	Centers for Medicare and Medicaid Services (CMS)
High Priority Measure:	No
Rationale:	Based on current evidence, the expert work group for the measure recommended revising the time frame for frequency of documenting BMI from 6 to 12 months. This proposed change doubles the time frame for numerator compliance, providing additional opportunities for meeting measure criteria. Extending the timeframe for numerator compliance will decrease the burden on the clinician, and can also potentially impact the performance rates.

E.5. Preventive Care and Screening: Influenza Immunization

Category	Description
NQF #:	0041
Quality #:	110
CMS E-Measure ID:	147v7
National Quality Strategy Domain:	Community/Population Health
Current Data Submission Method:	Claims, Web Interface, Registry, EHR
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization
Proposed Substantive Change:	Remove encounter count requirement from initial population. This change applies to the Registry and EHR data submission methods only.
Steward:	Physician Consortium for Performance Improvement (PCPI)
High Priority Measure:	No
Rationale:	The technical expert panel (TEP) convened by our measure development contractor recommended removing the 2-visit requirement from CMS147. The TEP suggests the measure should encourage clinicians to take advantage of every opportunity to administer the flu vaccination. CMS agrees with the TEP's recommendation and believes that each patient contact during the flu season is an opportunity to ensure that the patient received proper vaccination. This will reduce the number of missed opportunities for vaccination. We believe this proposed change allows clinicians to take advantage of every opportunity to administer the flu vaccination. In light of this change, the Initial Population language and the Initial Population logic need to be modified.

E.6. Use of High-Risk Medications in the Elderly

Category	Description
NQF #:	0022
Quality #:	238
CMS E-Measure ID:	156v6
National Quality Strategy Domain:	Patient Safety
Current Data Submission Method:	Registry, EHR
Current Measure Description:	Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.
Proposed Substantive Change:	The change is proposed in rate b, which will be going from two different medications to two instances of the same medication. This new change aligns with Beers criteria.
Steward:	National Committee for Quality Assurance (NCQA)
High Priority Measure:	Yes (Patient Safety)
Rationale:	The American Geriatrics Society has established the Beers criteria, inclusive of a list of medications considered to be inappropriate for elderly patients. The Beers criteria is important because it involves closer monitoring of drug use, application of real-time interventions, and better patient outcomes. The parent measure requires that the patients have two or more dispensing events (any days supply) on different dates of services during the measurement year. The dispensing events should be for the same drug (as identified by the drug ID in the HEDIS NDC code list).

E.7. Functional Status Assessment for Total Knee Replacement

Category	Description
NQF #:	N/A
Quality #:	375
CMS E-Measure ID:	66v6
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data Submission Method:	EHR
Current Measure Description:	Percentage of patients 18 years of age and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported functional status assessments
Proposed Substantive Change:	Aligning the initial population more closely with the measurement period. The overall duration of period remains the same. Changes to the measure description: Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Steward:	Centers for Medicare and Medicaid Services (CMS)
High Priority Measure:	Yes (Patient Experience)
Rationale:	The American Association of Hip and Knee Surgeons have recommended that the general/mental health survey be completed prior to surgery (during the preoperative visit) and after surgery (during the post-operative visit). The guidance calls for revised alignment with the measurement period.

E.8. Functional Status Assessment for Total Hip Replacement

Category	Description
NQF #:	N/A
Quality #:	376
CMS E-Measure ID:	56v6
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Data Submission Method:	EHR
Current Measure Description:	Percentage of patients 18 years of age and older with primary total hip arthroplasty (THA) who completed baseline and follow-up patient-reported functional status assessments
Proposed Substantive Change:	Revise timing to identify initial population, to align more closely with the measurement period. The overall duration of period remains the same. Changes to the measure descriptions: Percentage of patients 18 years of age and older with who received an elective primary total hip arthroplasty (THA) who completed baseline and follow-up patient-reported and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Steward:	Centers for Medicare and Medicaid Services (CMS)
High Priority Measure:	Yes (Patient Experience)
Rationale:	The American Association of Hip and Knee Surgeons have recommended that the general/mental health survey be completed prior to surgery (during the preoperative visit) and after surgery (during the post-operative visit). The guidance calls for revised alignment with the measurement period.

E.9. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF #:	N/A
Quality #:	438
CMS E-Measure ID:	347v1
National Quality Strategy Domain:	Effective Clinical Care
Current Data Submission Method:	Web Interface, Registry
Current Measure Description:	Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Proposed Substantive Change:	We propose to offer this measure as an eCQM for the 2018 performance period.
Steward:	Centers for Medicare and Medicaid Services (CMS)
High Priority Measure:	No
Rationale:	To provide eligible clinicians with an additional reporting option that can be used to report for the measure.

E.10. Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF #:	N/A
Quality #:	374
CMS E-Measure ID:	50v650v6
National Quality Strategy Domain:	Communication and Care Coordination
Current Data Submission Method:	EHR
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Proposed Substantive Change:	We propose to offer this measure as a registry measure for the 2018 performance period.
Steward:	Centers for Medicare and Medicaid Services (CMS)
High Priority Measure:	Yes (Care Coordination)
Rationale:	To provide eligible clinicians with an additional reporting option that can be used to report for the measure.

E.11. Dementia: Counseling Regarding Safety Concerns

Category	Description
NQF #:	N/A
Quality #:	286
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Data Submission Method:	Qualified Registry
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period
Proposed Substantive Change:	We propose to update the title, description and numerator of this measure to further specify the safety screening required and documentation of mitigation recommendations, consistent with updates from the measure steward.
Steward:	American Academy of Neurology
High Priority Measure:	Yes (Patient Safety)
Rationale:	CMS proposes to update this measure consistent with updates from the measure steward, as it will provide a more comprehensive assessment from which the results may provide additional insight about the patient's condition and alterations needed in the treatment plan therefore making this a more robust measure.

E.12. Dementia: Neuro-Psychiatric Symptom Assessment

Category	Description
NQF #:	N/A
Quality #:	283
CMS E-Measure ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Data Submission Method:	Qualified Registry
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12-month period
Proposed Substantive Change:	The measure was updated to change 'Functional Status Assessment and Results Reviewed' to 'Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management' Symptoms screening is for three domains 'activity disturbances', 'mood disturbances' and 'thought and perceptual disturbances' including depression. To meet the measure, a documented behavioral and psychiatric symptoms screen inclusive of at least one or more symptom from each of three defined domains AND documented symptom management recommendations if safety concerns screening is positive within the last 12 months.
Steward:	American Academy of Neurology
High Priority Measure:	No
Rationale:	The measure steward updated the measure to combine it with Q284: Dementia: Management of Neuropsychiatric Symptoms (proposed for removal), to make the measure more robust to include assessment of neuropsychiatric symptoms modified to include depression screening and the management of those symptoms.

Appendices—Improvement Activities Table

NOTE: For previously finalized improvement activities, we refer readers to the Finalized Improvement Activities Inventory in Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817). Except as otherwise proposed below, previously finalized improvement activities would continue to apply for the Quality Payment Program year 2 and future years.

TABLE F: Proposed New Improvement Activities for the Quality Payment Program Year 2 and Future Years

Activity ID:	**IA_AHE_XX**
Subcategory:	Achieving Health Equity
Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
Activity Description:	MIPS eligible clinician leadership in clinical trials, research alliances or community-based participatory research (CBPR) that identify tools, research or processes that can focuses on minimizing disparities in healthcare access, care quality, affordability, or outcomes.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_AHE_XX**
Subcategory:	Achieving Health Equity
Activity Title:	Provide Education Opportunities for New Clinicians
Activity Description:	MIPS eligible clinicians acting as a preceptor for clinicians-in-training (such as medical residents/fellows, medical students, physician assistants, nurse practitioners, or clinical nurse specialists) and accepting such clinicians for clinical rotations in community practices in small, underserved, or rural areas.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_BMH_XX**
Subcategory:	Behavioral and Mental Health
Activity Title:	Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
Activity Description:	Individual MIPS eligible clinicians or groups must regularly engage in integrated prevention and treatment interventions, including screening and brief counseling (for example: NQF #2152) for patients with co-occurring conditions of mental health and substance abuse. MIPS eligible clinicians would attest that 60 percent for the 2018 performance period, and 75 percent for the Quality Payment Program Year 2 and future years, of their ambulatory care patients are screened for unhealthy alcohol use.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_CC_XX**
Subcategory:	Care Coordination
Activity Title:	PSH Care Coordination
Activity Description:	Participation in a Perioperative Surgical Home (PSH) that provides a patient-centered, physician-led, interdisciplinary, and team-based system of coordinated patient care, which coordinates care from pre-procedure assessment through the

	acute care episode, recovery, and post-acute care. This activity allows for reporting of strategies and processes related to care coordination of patients receiving surgical or procedural care within a PSH. The clinician must perform one or more of the following care coordination activities: • Coordinate with care managers/navigators in preoperative clinic to plan and implementation comprehensive post discharge plan of care; • Deploy perioperative clinic and care processes to reduce post-operative visits to emergency rooms; • Implement evidence-informed practices and standardize care across the entire spectrum of surgical patients; or • Implement processes to ensure effective communications and education of patients' post-discharge instructions.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Activity ID:	**IA_CC_XX**
Subcategory:	Care Coordination
Activity Title:	Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients
Activity Description:	The primary care and behavioral health practices use the same electronic health record system for shared patients or have an established bidirectional flow of primary care and behavioral health records.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes, if accomplished with CEHRT
Activity ID:	**IA_EPA_XX**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Participation in User Testing of the Quality Payment Program Website (https://qpp.cms.gov/)
Activity Description:	User participation in the Quality Payment Program website testing is an activity for eligible clinicians who have worked with CMS to provided substantive, timely, and responsive input to improve the CMS Quality Payment Program website through product user-testing that enhances system and program accessibility, readability and responsiveness as well as providing feedback for developing tools and guidance thereby allowing for a more user-friendly and accessible clinician and practice Quality Payment Program website experience.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Participation in Population Health Research
Activity Description:	Participation in federally and/or privately funded research that identifies interventions, tools, or processes that can improve a targeted patient population.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Provide Clinical-Community Linkages

Activity Description:	Engaging community health workers to provide a comprehensive link to community resources through family-based services focusing on success in health, education, and self-sufficiency. This activity supports individual MIPS eligible clinicians or groups that coordinate with primary care and other clinicians, engage and support patients, use of health information technology, and employ quality measurement and improvement processes. An example of this community based program is the NCQA Patient-Centered Connected Care (PCCC) Recognition Program or other such programs that meet these criteria.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes, if accomplished with CEHRT
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Glycemic Screening Services
Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 75 percent of electronic medical records with documentation of screening patients for abnormal blood glucose according to current US Preventive Services Task Force (USPSTF) and/or American Diabetes Association (ADA) guidelines.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Glycemic Referring Services
Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 75 percent of medical records with documentation of referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Activity ID:	**IA_PM_XX**
Subcategory:	Population Management
Activity Title:	Advance Care Planning
Activity Description:	Implementation of practices/processes to develop advance care planning that includes: documenting the advance care plan or living will within the medical record, educating clinicians about advance care planning motivating them to address advance care planning needs of their patients, and how these needs can translate into quality improvement, educating clinicians on approaches and barriers to talking to patients about end-of-life and palliative care needs and ways to manage its documentation, as well as informing clinicians of the healthcare policy side of advance care planning.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes

Activity ID:	**IA_PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
Activity Description:	Completion of all the modules of the Centers for Disease Control and Prevention (CDC) course "Applying CDC's Guideline for Prescribing Opioids" that reviews the 2016 "Guideline for Prescribing Opioids for Chronic Pain." Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_ PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Completion of CDC Training on Antibiotic Stewardship
Activity Description:	Completion of all modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_ PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Initiate CDC Training on Antibiotic Stewardship
Activity Description:	Completion of greater than 50 percent of the modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_ PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Cost Display for Laboratory and Radiographic Orders
Activity Description:	Implementation of a cost display for laboratory and radiographic orders, such as costs that can be obtained through the Medicare clinical laboratory fee schedule.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No

Activity ID:	**IA_PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Communication of Unscheduled Visit for Adverse Drug Event and Nature of Event
Activity Description:	A MIPS eligible clinician providing unscheduled care (such as an emergency room, urgent care, or other unplanned encounter) attests that, for greater than 75 percent of case visits that result from a clinically significant adverse drug event, the MIPS eligible clinician provides information, including through the use of health IT to the patient's primary care clinician regarding both the unscheduled visit and the nature of the adverse drug event within 48 hours. A clinically significant adverse event is defined as a medication-related harm or injury such as side-effects, supratherapeutic effects, allergic reactions, laboratory abnormalities, or medication errors requiring urgent/emergent evaluation, treatment, or hospitalization.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Activity ID:	**IA_ PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Invasive Procedure or Surgery Anticoagulation Medication Management
Activity Description:	For an anticoagulated patient undergoing a planned invasive procedure for which interruption in anticoagulation is anticipated, including patients taking vitamin K antagonists (warfarin), target specific oral anticoagulants (such as apixaban, dabigatran, and rivaroxaban), and heparins/low molecular weight heparins, documentation, including through the use of electronic tools, that the plan for anticoagulation management in the periprocedural period was discussed with the patient and with the clinician responsible for managing the patient's anticoagulation. Elements of the plan should include the following: discontinuation, resumption, and, if applicable, bridging, laboratory monitoring, and management of concomitant antithrombotic medications (such as antiplatelets and nonsteroidal anti-inflammatory drugs (NSAIDs)). An invasive or surgical procedure is defined as a procedure in which skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Activity Description:	Completion of an accredited performance improvement continuing medical education program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and

	• The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Activity ID:	**IA_PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Consulting AUC Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging
Activity Description:	Clinicians attest that they are consulting specified applicable appropriate use criteria (AUC) through a qualified clinical decision support mechanism for all advanced diagnostic imaging services ordered. This activity is for clinicians that are early adopters of the Medicare AUC program (e.g., 2018 performance year) and for clinicians that begin the Medicare AUC program in future years will be required by §414.94 (authorized by the Protecting Access to Medicare Act of 2014). Qualified mechanisms will be able to provide a report to the ordering clinician that can be used to assess patterns of image-ordering and improve upon those patterns to ensure that patients are receiving the most appropriate imaging for their individual condition.
Weighting:	High
Eligible for Advancing Care Information Bonus:	Yes
Activity ID:	**IA_PSPA_XX**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	PCI Bleeding Campaign
Activity Description:	Participation in the PCI Bleeding Campaign which is a national quality improvement program that provides infrastructure for a learning network and offers evidence-based resources and tools to reduce avoidable bleeding associated with patients who receive a percutaneous coronary intervention (PCI). The program uses a patient-centered and team-based approach, leveraging evidence-based best practices to improve care for PCI patients by implementing quality improvement strategies: • Radial-artery access, • Bivalirudin, and • Use of vascular closure devices.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No

We propose to include these additional improvement activities in the Improvement Activities Inventory for the Quality Payment Program Year 2 and future years based on guidelines discussed in the CY 2017 Quality Payment Program final rule at (81 FR 77190) and proposed in section II.C.6.e.(7)(b) of this proposed rule. These may include one or more of the following criteria:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Activities that may be considered for an advancing care information bonus;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- CMS is able to validate the activity; or
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.

TABLE G: Proposed Improvement Activities with Changes for the Quality Payment Program Year 2 and Future Years

Activity ID:	**IA_AHE_1**
Subcategory:	Achieving Health Equity
Activity Title:	Engagement of New Medicaid Patients and Follow-up
Current Activity Description:	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare. A timely manner is defined as within 10 business days for this activity.
Rationale:	We propose to revise the wording of this improvement activity to clarify the meaning of "a timely manner."
Activity ID:	**IA_AHE_3**
Subcategory:	Achieving Health Equity
Activity Title:	Leveraging a QCDR to Promote Use of PRO Tools
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Change Activity Title to: Promote Use of Patient-Reported Outcome Tools Change Activity Description to: Demonstrate performance of activities for employing patient-reported outcome (PRO) tools and corresponding collection of PRO data such as the use of PQH-2 or PHQ-9, PROMIS instruments, patient reported Wound Quality of Life (QoL), patient reported Wound Outcome, and patient reported Nutritional Screening Change Weight to: High Proposed change to eligibility for advancing care information bonus: Change to "yes" for eligible for advancing care information bonus. We believe MIPS eligible clinicians may utilize EHR to capture this information to include standardized data capture and incorporating patient generated health data.
Rationale:	We propose to revise this improvement activity to expand its application to include employing the PRO tools and corresponding collection of PRO data. In addition, we propose to provide additional examples of activities that may be appropriate for this improvement activity.
Activity ID:	**IA_BE_14**
Subcategory:	Beneficiary Engagement
Activity Title:	Engage Patients and Families to Guide Improvement in the System of Care
Current Activity Description:	Engage patients and families to guide improvement in the system of care.
Weighting:	High
Eligible for Advancing Care Information Bonus:	Yes

Proposed Change:	Engage patients and families to guide improvement in the system of care by leveraging digital tools for ongoing guidance and assessments outside the encounter, including the collection and use of patient data for return-to-work and patient quality of life improvement. Platforms and devices that collect patient-generated health data (PGHD) must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient, including patient reported outcomes (PROs). Examples include patient engagement and outcomes tracking platforms, cellular or web-enabled bi-directional systems, and other devices that transmit clinically valid objective and subjective data back to care teams. Because many consumer-grade devices capture PGHD (for example, wellness devices), platforms or devices eligible for this improvement activity must be, at a minimum, endorsed and offered clinically by care teams to patients to automatically send ongoing guidance (one way). Platforms and devices that additionally collect PGHD must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient (e.g. automated patient-facing instructions based on glucometer readings). Therefore, unlike passive platforms or devices that may collect but do not transmit PGHD in real or near-real time to clinical care teams, active devices and platforms can inform the patient or the clinical care team in a timely manner of important parameters regarding a patient's status, adherence, comprehension, and indicators of clinical concern.
Rationale:	Proposed activity description: We believe that the use of digital technologies that provide either one-way or two-way data between MIPS eligible clinicians and patients is valuable, including for the purposes of promoting patient self-management, enabling remote monitoring, and detecting early indicators of treatment failure. Proposed weight: Change to high because of increased cost and time considerations for digital tools for ongoing guidance and assessment outside of encounter. Proposed change to eligibility for advancing care information bonus: Change to "yes" for eligible for advancing care information bonus. We believe MIPS eligible clinicians will use health IT including providing patients access to health information and educational resources as well as incorporating PGHD for this activity to include standardized data capture and incorporating patient generated health data.
Activity ID:	**IA_BE_15**
Subcategory:	Beneficiary Engagement
Activity Title:	Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
Current Activity Description:	Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the certified electronic health record (EHR) technology.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the electronic health record (EHR) technology.
Rationale:	We propose to remove the requirement that the EHR technology be certified.

	We do not believe this improvement activity should be limited to certified EHR technology, however, when certified technology is used, eligible clinicians may qualify for the advancing care information bonus.
Activity ID:	**IA_BE_21**
Subcategory:	Beneficiary Engagement
Activity Title:	Improved Practices that Disseminate Appropriate Self-Management Materials
Current Activity Description:	Provide self-management materials at an appropriate literacy level and in an appropriate language.
Weighting:	Medium
Current Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	We propose to correct the "eligible for advancing care information bonus" for this improvement activity to "No."
Rationale:	This improvement activity contains an error and should not include an advancing care information bonus indicator.
Activity ID:	**IA_BE_22**
Subcategory:	Beneficiary Engagement
Activity Title:	Improved Practices that Engage Patients Pre-Visit
Current Activity Description:	Provide a pre-visit development of a shared visit agenda with the patient.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Implementation of workflow changes that engage patients prior to the visit, such as a pre-visit development of a shared visit agenda with the patient, or targeted pre-visit laboratory testing that will be resulted and available to the MIPS eligible clinician to review and discuss during the patient's appointment.
Rationale:	We propose to clarify the type of actions that qualify for this improvement activity.
Activity ID:	**IA_BMH_7**
Subcategory:	Behavioral and Mental Health
Activity Title:	Implementation of Integrated Patient Centered Behavioral Health Model
Current Activity Description:	Offer integrated behavioral health services to support patients with behavioral health needs, dementia, and poorly controlled chronic conditions that could include one or more of the following: • Use evidence-based treatment protocols and treatment to goal where appropriate; • Use evidence-based screening and case finding strategies to identify individuals at risk and in need of services; • Ensure regular communication and coordinated workflows between eligible clinicians in primary care and behavioral health; • Conduct regular case reviews for at-risk or unstable patients and those who are not responding to treatment; • Use of a registry or health information technology functionality to support active care management and outreach to patients in treatment; and/or integrate behavioral health and medical care plans and facilitate integration through co-location of services when feasible.

Weighting:	High
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Offer integrated behavioral health services to support patients with behavioral health needs who also have conditions such as dementia or other poorly controlled chronic illnesses. The services could include one or more of the following: • Use evidence-based treatment protocols and treatment to goal where appropriate; • Use evidence-based screening and case finding strategies to identify individuals at risk and in need of services; • Ensure regular communication and coordinated workflows between MIPS eligible clinicians in primary care and behavioral health; • Conduct regular case reviews for at-risk or unstable patients and those who are not responding to treatment; • Use of a registry or health information technology functionality to support active care management and outreach to patients in treatment; and/or integrate behavioral health and medical care plans and facilitate integration through co-location of services when feasible. • Participate in the National Partnership to Improve Dementia Care Initiative, which promotes a multidimensional approach that includes public reporting, state-based coalitions, research, training, and revised surveyor guidance.
Rationale:	We propose to revise the wording of this improvement activity to clarify that the list of chronic illnesses is not limited to these examples.
Activity ID:	**IA_CC_1**
Subcategory:	Care Coordination
Activity Title:	Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
Current Activity Description:	Performance of regular practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Performance of regular practices that include providing specialist reports back to the referring individual MIPS eligible clinician or group to close the referral loop or where the referring individual MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the EHR technology.
Rationale:	We propose to remove the requirement that the EHR technology be certified. We do not believe this improvement activity should be limited to certified EHR technology, however, when certified technology is used, eligible clinicians may qualify for the advancing care information bonus.
Activity ID:	**IA_CC_4**
Subcategory:	Care Coordination
Activity Title:	TCPI Participation

Current Activity Description:	Participation in the CMS Transforming Clinical Practice Initiative
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	We propose to change the weight of this improvement activity from high to medium for MIPS Year 2 and future years.
Rationale:	We designated this activity as a high-weighted activity for the transition year of MIPS. However, we note that MIPS eligible clinicians that participate in the CMS Transforming Clinical Practice Initiative (TCPI)—which is an APM (as defined in section 1833(z)(3)(C) of the Act)—will automatically earn a minimum score of one-half of the highest potential score for this performance category, as required by section 1848(q)(5)(C)(ii) of the Act. In addition, we anticipate that most MIPS eligible clinicians that are fully active TCPI participants will participate in additional practice improvement activities and will be able to select additional improvement activities to achieve the improvement activities highest score.
Activity ID:	**IA_CC_9**
Subcategory:	Care Coordination
Activity Title:	Implementation of practices/processes for developing regular individual care plans
Current Activity Description:	Implementation of practices/processes to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s).
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Implementation of practices/processes, including a discussion on care, to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s). Individual care plans should include consideration of a patient's goals and priorities, as well as desired outcomes of care.
Rationale:	We propose this revision because by having an open conversation on care, we believe patients and MIPS eligible clinicians can work together to evaluate care options and opportunities that are based on an individual patient's values and priorities.
Activity ID:	**IA_CC_13**
Subcategory:	Care Coordination
Activity Title:	Practice Improvements for Bilateral Exchange of Patient Information
Current Activity Description:	Ensure that there is bilateral exchange of necessary patient information to guide patient care that could include one or more of the following: • Participate in a Health Information Exchange if available; and/or • Use structured referral notes.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Ensure that there is bilateral exchange of necessary patient information to guide patient care, such as Open Notes, that could include one or more of the following: • Participate in a Health Information Exchange if available; and/or

	• Use structured referral notes.
Rationale:	We propose to provide additional examples of activities that would qualify for this improvement activity.
Activity ID:	**IA_CC_14**
Subcategory:	Care Coordination
Activity Title:	Practice Improvements that Engage Community Resources to Support Patient Health Goals
Current Activity Description:	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: • Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; and/or provide a guide to available community resources.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: • Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; • Including through the use of tools that facilitate electronic communication between settings; • Screen patients for health-harming legal needs; • Screen and assess patients for social needs using tools that are preferably health IT enabled and that include to any extent standards-based, coded question/field for the capture of data as is feasible and available as part of such tool; and/or • Provide a guide to available community resources.
Rationale:	We propose to add screening patients for health harming legal needs to this activity, as such screening can help MIPS eligible clinicians address the social determinants that contribute to the most challenging problems related to coordinating care. In addition, we propose to change the eligible for advancing care information bonus to "yes." We believe MIPS eligible clinicians may use EHR to communicate with community-based resources including secure messaging, sending and receiving summary of care records, and incorporating data from a non-clinical setting.
Activity ID:	**IA_EPA_1**
Subcategory:	Expanded Practice Access
Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Current Activity Description:	• Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible

	clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Weighting:	High
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	We propose to change the weight of this improvement activity from high to medium for MIPS Year 2 and future years. In addition, we are proposing to change the language to this improvement activity as follows: • Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (for example, eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (for example, coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by individual MIPS eligible clinicians and groups, such as telehealth, phone visits, group visits, home visits and alternate locations (for example, senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Rationale:	We designated this activity as a high-weighted activity for the transition year of MIPS. However, we are seeking comment on why this activity should either maintain the current weight or why the weighting should be decreased to medium.
Activity ID:	**IA_PM_1**
Subcategory:	Population Management
Activity Title:	Participation in Systematic Anticoagulation Program
Current Activity Description:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in year 2 who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Rationale:	We propose to clarify that the 75 percent performance target extends into future

	years.
Activity ID:	**IA_PM_2**
Subcategory:	Population Management
Activity Title:	Anticoagulant Management Improvements
Current Activity Description:	MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, in the first performance year, 60 percent or more of their ambulatory care patients receiving warfarin are being managed by one or more of these clinical practice improvement activities: • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care*, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program. MIPS eligible clinicians would attest that, 60 percent for the transition year or 75 percent for the second year, of their ambulatory care patients receiving warfarin participated in an anticoagulation management program for at least 90 days during the performance period.
Weighting:	High
Eligible for Advancing Care Information Bonus:	Yes
Proposed Change:	Individual MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, 75 percent or more of their ambulatory care patients receiving warfarin are being managed by one or more of the following improvement activities: • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or

	• For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Rationale:	We propose to clarify which actions qualify for this improvement activity for the Quality Payment Program Year 2 and future years.
Activity ID:	**IA_PM_8**
Subcategory:	Population Management
Activity Title:	Participation in CMMI models such as the Million Hearts Campaign
Current Activity Description:	Participation in CMMI models such as the Million Hearts Cardiovascular Risk Reduction Model
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Delete activity from the improvement activities inventory.
Rationale:	We do not believe participants in an APM, who have already automatically received 50% credit in the improvement activity performance category, should be provided additional credit for this improvement activity based solely on their participation in a single APM.
Activity ID:	**IA_PM_11**
Subcategory:	Population Management
Activity Title:	Regular Review Practices in Place on Targeted Patient Population Needs
Current Activity Description:	Implementation of regular reviews of targeted patient population needs which includes access to reports that show unique characteristics of eligible professional's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Implementation of regular reviews of targeted patient population needs, such as structured clinical case reviews, which includes access to reports that show unique characteristics of eligible clinician's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.
Rationale:	We propose to provide additional examples of activities that would qualify for this improvement activity.
Activity ID:	**IA_PM_13**
Subcategory:	Population Management
Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Current Activity Description:	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following: • Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; plan of care for chronic conditions; and advance care planning;

	• Use condition-specific pathways for care of chronic conditions (e.g., hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; • Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; • Use panel support tools (registry functionality) to identify services due; • Use predictive analytical models to predict risk, onset and progression of chronic diseases; or • Use reminders and outreach (e.g., phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or Routine medication reconciliation.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following: • Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; • Use condition-specific pathways for care of chronic conditions (e.g., hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; • Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; • Use panel support tools (registry functionality) to identify services due; • Use predictive analytical models to predict risk, onset and progression of chronic diseases; or • Use reminders and outreach (e.g., phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Rationale:	We propose to remove the advance care planning portion of this improvement activity. We are proposing to create a new improvement activity focused on advance care planning.
Activity ID:	**IA_PSPA_2**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Participation in MOC Part IV
Current Activity Description:	Participation in Maintenance of Certification (MOC) Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Participation in Maintenance of Certification (MOC) Part IV, such as the

	American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or ASA Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Rationale:	We propose to provide additional examples of activities that would qualify for this improvement activity.
Activity ID:	**IA_PSPA_3**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Participate in IHI Training/Forum Event; National Academy of Medicine, AHRQ Team STEPPS® or Other Similar Activity
Current Activity Description:	For eligible professionals not participating in Maintenance of Certification (MOC) Part IV, new engagement for MOC Part IV, such as IHI Training/Forum Event; National Academy of Medicine, AHRQ Team STEPPS®.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	For MIPS eligible clinicians not participating in Maintenance of Certification (MOC) Part IV, new engagement for MOC Part IV, such as the Institute for Healthcare Improvement (IHI) Training/Forum Event; National Academy of Medicine, Agency for Healthcare Research and Quality (AHRQ) Team STEPPS®, or the American Board of Family Medicine (ABFM) Performance in Practice Modules.
Rationale:	We propose to revise this improvement activity to clarify that other MOC programs are eligible for this improvement activity.
Activity ID:	**IA_PSPA_4**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Administration of the AHRQ Survey of Patient Safety Culture
Current Activity Description:	Administration of the AHRQ Survey of Patient Safety Culture and submission of data to the comparative database (refer to AHRQ Survey of Patient Safety Culture website http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html).
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Administration of the AHRQ Survey of Patient Safety Culture and submission of data to the comparative database (refer to AHRQ Survey of Patient Safety Culture website http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html). Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Rationale:	We propose to revise the wording of this improvement activity to specify that it may be selected once every 4 years to achieve the performance category score.

Activity ID:	**IA_PSPA_6**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Consultation of the Prescription Drug Monitoring Program
Current Activity Description:	Clinicians would attest that 60 percent for the first year, or 75 percent for the second year, of consultation of prescription drug monitoring program prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than 3 days.
Weighting:	High
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Clinicians would attest to reviewing the patients' history of controlled substance prescription using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. For the transition year, clinicians would attest to 60 percent review of applicable patient's history. For the Quality Payment Program Year 2 and future years, clinicians would attest to 75 percent review of applicable patient's history performance.
Rationale:	We propose to clarify that in the transition year, clinicians would attest to 60 percent review of applicable patient's history. In the Quality Payment Program Year 2 and future years, clinicians would attest to 75 percent review of applicable patient's history performance.
Activity ID:	**IA_PSPA_8**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Use of Patient Safety Tools
Current Activity Description:	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the surgical risk calculator.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of a surgical risk calculator, evidence based protocols such as Enhanced Recovery After Surgery (ERAS) protocols, the CDC Guide for Infection Prevention for Outpatient Settings, (https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html), predictive algorithms, or other such tools.
Rationale:	We propose to include additional examples of tools that may be utilized to assist specialty practices in tracking specific measures that are meaningful to their practice, including evidence based protocols such as Enhanced Recovery After Surgery (ERAS) protocols, the CDC Guide for Infection Prevention for Outpatient Settings and the use of tools and protocols that promote appropriate use criteria.
Activity ID:	**IA_PSPA_14**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Participation in Bridges to Excellence or Other Similar Programs
Current Activity Description:	Participation in other quality improvement programs such as Bridges to Excellence.
Weighting:	Medium

Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Proposed Activity Title: Participation in Quality Improvement Initiatives Proposed Activity Description: Participation in other quality improvement programs such as Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Rationale:	We propose to revise the wording of this improvement activity to clarify that other programs are eligible for this improvement activity.
Activity ID:	**IA_PSPA_15**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Implementation of an ASP
Current Activity Description:	Implementation of an antibiotic stewardship program that measures the appropriate use of antibiotics for several different conditions (URI Rx in children, diagnosis of pharyngitis, Bronchitis Rx in adults) according to clinical guidelines for diagnostics and therapeutics.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Leadership of an Antimicrobial Stewardship Program (ASP) that includes implementation of an ASP that measures the appropriate use of antibiotics for several different conditions (such as upper respiratory infection treatment in children, diagnosis of pharyngitis, bronchitis treatment in adults) according to clinical guidelines for diagnostics and therapeutics. Specific activities may include: • Develop facility-specific antibiogram and prepare report of findings with specific action plan that aligns with overall hospital strategic plan. • Lead the development, implementation, and monitoring of patient care and patient safety protocols for the delivery of ASP including protocols pertaining to the most appropriate setting for such services (i.e., outpatient or inpatient). • Assist in improving ASP service line efficiency and effectiveness by evaluating and recommending improvements in the management structure and workflow of ASP processes. • Manage compliance of the ASP policies and assist with implementation of corrective actions in accordance with hospital compliance policies and hospital medical staff by-laws. • Lead the education and training of professional support staff for the purpose of maintaining an efficient and effective ASP. • Coordinate communications between ASP management and hospital personnel regarding activities, services, and operational/clinical protocols to achieve overall compliance and understanding of the ASP. • Assist, at the request of the hospital, in preparing for and responding to third-party requests, including but not limited to payer audits, governmental inquiries, and professional inquiries that pertain to the ASP service line.
Rationale:	We propose to provide additional examples of activities that may be appropriate for this improvement activity.
Activity ID:	**IA_PSPA_18**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Measurement and Improvement at the Practice and Panel Level

Current Activity Description:	Measure and improve quality at the practice and panel level that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or • Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No
Proposed Change:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards, that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or • Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
Rationale:	We propose to provide additional examples of activities that may be appropriate for this improvement activity.
Activity ID:	**IA_PSPA_19**
Subcategory:	Patient Safety & Practice Assessment
Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following: • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.
Weighting:	Medium
Eligible for Advancing Care Information Bonus:	No

Proposed Change:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following such as: • Multi-Source Feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.
Rationale:	We propose to provide additional examples of activities that would qualify for this improvement activity.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Removing the Greater Yellowstone Ecosystem Population of Grizzly Bears From the Federal List of Endangered and Threatened Wildlife; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2016–0042; FXES11130900000C6–178–FF09E42000]

RIN 1018–BA41

Endangered and Threatened Wildlife and Plants; Removing the Greater Yellowstone Ecosystem Population of Grizzly Bears From the Federal List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; availability of final Grizzly Bear Recovery Plan Supplement: Revised Demographic Criteria.

SUMMARY: The best available scientific and commercial data indicate that the Greater Yellowstone Ecosystem (GYE) population of grizzly bears (*Ursus arctos horribilis*) is a valid distinct population segment (DPS) and that this DPS has recovered and no longer meets the definition of an endangered or threatened species under the Endangered Species Act, as amended (Act). Therefore, we, the U.S. Fish and Wildlife Service (Service), hereby revise the List of Endangered and Threatened Wildlife, under the authority of the Act, by establishing a DPS and removing the GYE grizzly bear DPS. The Service has determined that the GYE grizzly bear population has increased in size and more than tripled its occupied range since being listed as threatened under the Act in 1975 and that threats to the population are sufficiently minimized. The participating States of Idaho, Montana, and Wyoming and Federal agencies have adopted the necessary post-delisting plans and regulations, which adequately ensure that the GYE population of grizzly bears remains recovered.

Concurrent to this final rule, we are appending the Grizzly Bear Recovery Plan Supplement: Revised Demographic Criteria to the 1993 Recovery Plan. Moreover, prior to publication of this final rule, the Yellowstone Ecosystem Subcommittee finalized the 2016 Conservation Strategy that will guide post-delisting monitoring and management of the grizzly bear in the GYE. Additionally, the U.S. Forest Service finalized in 2006 the Forest Plan Amendment for Grizzly Bear Conservation for the GYE National Forests and made a decision to incorporate this Amendment into the affected National Forests' Land Management Plans. Yellowstone National Park and Grand Teton National Park appended the habitat standards to their Park Superintendent's Compendia, thereby ensuring that these national parks would manage habitat in accordance with the habitat standards. The States of Idaho, Montana, and Wyoming have signed a Tri-State Memorandum of Agreement and enacted regulatory mechanisms to ensure that State management of mortality limits is consistent with the demographic recovery criteria.

DATES: This final rule becomes effective July 31, 2017.

ADDRESSES: Comments and materials received, as well as supporting documentation used in preparation of this final rule, are available for inspection, by appointment, during normal business hours, at the Grizzly Bear Recovery Office, University Hall, Room #309, University of Montana, Missoula, Montana 59812. To make arrangements, call 406–243–4903.

Document availability: This final rule and supporting documents are available on *http://www.regulations.gov* under Docket No. FWS–R6–ES–2016–0042. In addition, certain documents, such as the final 2016 Conservation Strategy, the final Grizzly Bear Recovery Plan Supplement: Revised Demographic Criteria, and a list of references cited, are available at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php.* The Service will complete the decision file shortly.

FOR FURTHER INFORMATION CONTACT: Dr. Hilary Cooley, Grizzly Bear Recovery Coordinator, U.S. Fish and Wildlife Service, University Hall, Room #309, University of Montana, Missoula, MT 59812; telephone 406–243–4903; facsimile 406–329–3212. For Tribal inquiries, contact Roya Mogadam, Deputy Assistant Regional Director, External Affairs, U.S. Fish and Wildlife Service; telephone: 303–236–4572. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

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Executive Summary

(1) Purpose of the Regulatory Action

Section 4 of the Act and its implementing regulations in part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth the procedures for revising the Federal Lists of Endangered and Threatened Wildlife and Plants. Rulemaking is required to remove a species from these lists. Accordingly, we are issuing this final rule to identify the Greater Yellowstone Ecosystem (GYE) grizzly bear distinct population segment (DPS) and revise the List of Endangered and Threatened Wildlife by removing the DPS from the List. The population is stable (*i.e.,* no statistical trend in the population trajectory), threats are sufficiently ameliorated, and a post-delisting monitoring and management framework has been developed and has been incorporated into regulatory mechanisms or other operative documents. The best scientific and commercial data available, including our detailed evaluation of information related to the population's trend and structure, indicate that the GYE grizzly bear DPS has recovered and threats have been reduced such that it no longer meets the definition of threatened, or endangered, under the Act. To better articulate demographic criteria that adequately describe a recovered population, we are releasing a supplement to the 1993 Recovery Plan's demographic recovery criteria for this population of grizzly bears. In addition, the 2016 Conservation Strategy was finalized and signed by all partner agencies in December 2016. Identifying the GYE grizzly bear DPS and removing that DPS from the List of Endangered and Threatened Wildlife does not change the threatened status of the remaining grizzly bears in the lower 48 States, which remain protected by the Act.

On September 21, 2009, the U.S. District Court for the District of Montana vacated and remanded the Service's previous final rule establishing and delisting this DPS. The Ninth Circuit Court of Appeals affirmed the district court finding that the Service had not adequately analyzed the effects of whitebark pine as a food source for this DPS, but reversed the district court finding that the Service had permissibly and appropriately considered the 2007 Conservation Strategy under section 4 of the Act. *Greater Yellowstone Coalition* v. *Servheen,* 665 F.3d 1015 (9th Cir. 2011). This final rule completes that remand order by addressing the effects of whitebark pine, as well as the other applicable factors under section 4 of the Act.

(2) Major Provision of the Regulatory Action

This action is authorized by the Act. We are amending 50 CFR 17.11(h) by revising the listing for ''Bear, grizzly'' under ''Mammals'' in the List of Endangered and Threatened Wildlife to remove the GYE grizzly bear DPS.

(3) Costs and Benefits

We have not analyzed the costs or benefits of this rulemaking action because the Act precludes consideration of such impacts on listing and delisting determinations. Instead, listing and delisting decisions are based solely on the best scientific and commercial data available regarding the status of the subject species.

Greater Yellowstone Ecosystem (GYE)

The Greater Yellowstone Ecosystem (GYE) refers to the larger ecological system containing and surrounding Yellowstone National Park (YNP). The GYE includes portions of five National Forests; YNP, Grand Teton National Park (GTNP), and the John D. Rockefeller Memorial Parkway (JDR; administered by GTNP); and State, Tribal, and private lands. The GYE is generally defined as those lands surrounding YNP with elevations greater than 1,500 meters (m) (4,900 feet (ft)) (see USDA FS 2004, p. 46; Schwartz *et al.* 2006b, p. 9). While we consider the terms ''Greater Yellowstone Area'' and ''Greater Yellowstone Ecosystem'' to be interchangeable, we use GYE in this final rule to be consistent with the 2016 Conservation Strategy. The Primary Conservation Area (PCA) boundary is the same as and replaces the existing Yellowstone Recovery Zone as identified in the *1993 Grizzly Bear Recovery Plan* (USFWS 1993, p. 41) to reflect the paradigm shift from managing for recovery as a listed species under the Act to one of conservation as a non-listed species (figure 1). Monitoring of the demographic criteria for the GYE grizzly bear population will occur, by the Interagency Grizzly Bear Study Team (IGBST), within the demographic monitoring area (DMA) to ensure a recovered population (figure 1).

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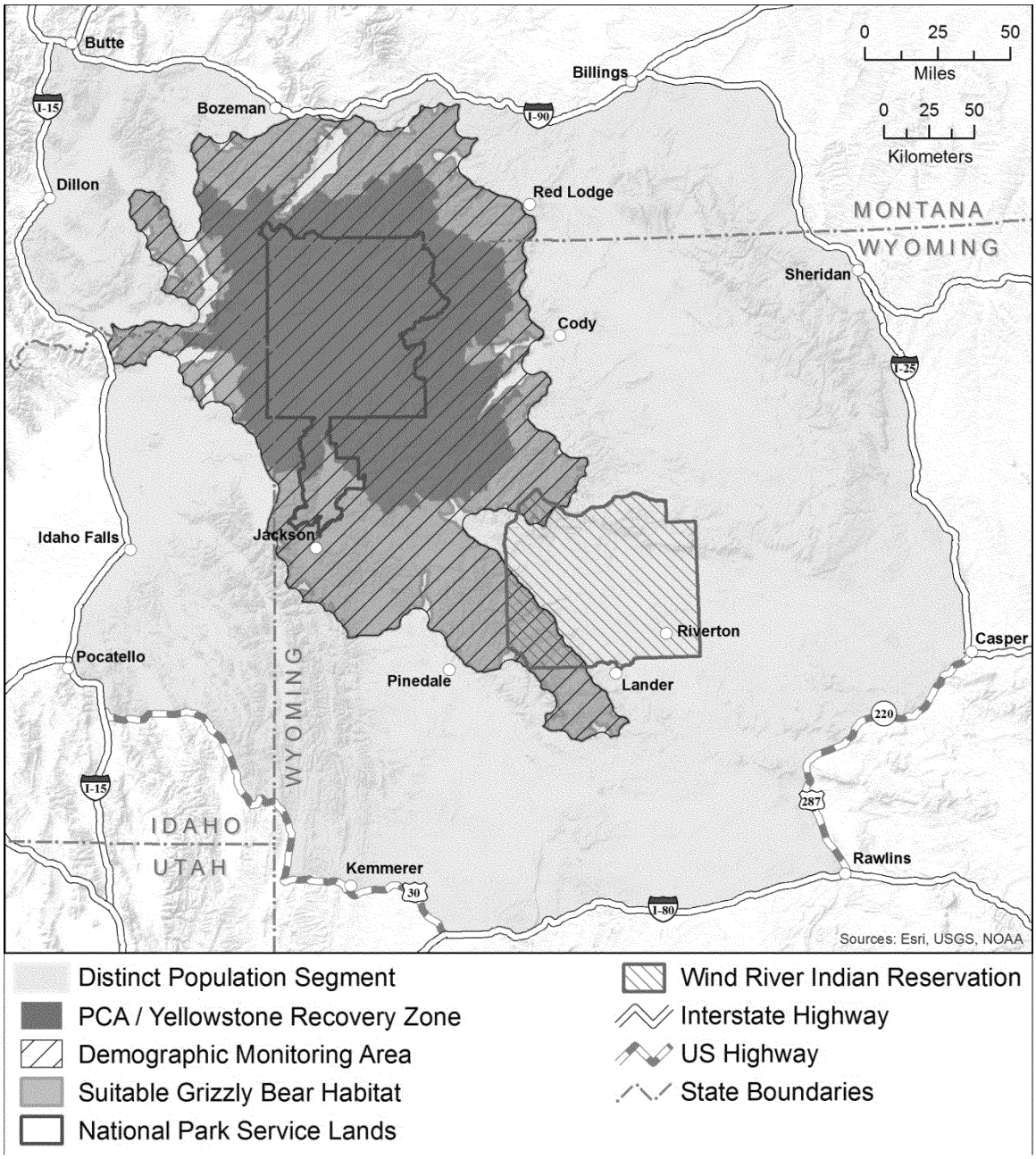

Figure 1. Map of the Greater Yellowstone Ecosystem (GYE). Boundaries are shown for: (1) the GYE grizzly bear Distinct Population Segment; (2) the Primary Conservation Area; (3) the Demographic Monitoring Area; (4) biologically suitable habitat (as defined in Factor A, below); and (5) National Park Service lands. An interactive map of the GYE boundaries is available at *http://usgs.maps.arcgis.com/home/webmap/viewer.html?webmap=78152b8e0bde457ca95918fdd48c5352.*

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Previous Federal Actions

On July 28, 1975, we published a rule to designate the grizzly bear as threatened in the conterminous (lower 48) United States (40 FR 31734). Accordingly, we developed a Grizzly Bear Recovery Plan (U.S. Fish and Wildlife Service 1982) and updated that plan as necessary (72 FR 11376, March 13, 2007; U.S. Fish and Wildlife Service 1993, 2007*a,* 2007*b,* 2017). On November 17, 2005, we proposed to designate the GYE population of grizzly

bears as a DPS and to remove (delist) this DPS from the Federal List of Endangered and Threatened Wildlife (70 FR 69854). On March 29, 2007, we finalized this proposed action, designating the GYE population as a DPS and removing (delisting) grizzly bears in the GYE from the Federal List of Endangered and Threatened Wildlife (72 FR 14866). This final determination was vacated and remanded by the U.S. District Court for the District of Montana on September 21, 2009, in *Greater Yellowstone Coalition* v. *Servheen, et al.,* 672 F.Supp.2d 1105 (D. Mont. 2009). The District Court ruled against the Service on two of the four points brought against it: That the Service was arbitrary and capricious in its evaluation of whitebark pine and that the identified regulatory mechanisms were inadequate because they were not legally enforceable. In compliance with this order, the GYE grizzly bear population was once again made a threatened population under the Act (16 U.S.C. 1531 *et seq.*) (see 75 FR 14496, March 26, 2010), and the Service withdrew the delisting rule.

The Service appealed the District Court decision, and on November 15, 2011, the Ninth Circuit Court of Appeals issued an opinion affirming in part and reversing in part the district court's decision vacating and remanding the final rule delisting grizzly bears in the Greater Yellowstone Ecosystem (*Greater Yellowstone Coalition* v. *Servheen, et al.,* 665 F.3d 1015 (9th Cir. 2011)). The Ninth Circuit held that the Service's consideration of the regulatory mechanisms was permissible, but that the Service inadequately explained why the loss of whitebark pine was not a threat to the GYE grizzly bear population. In compliance with this order, the GYE population of grizzly bears remained federally listed as ''threatened'' under the Act, and the IGBST initiated more thorough research into the potential impact of whitebark pine decline on GYE grizzly bears. In this final rule, among the other findings, we respond to the District Court's remand and the Ninth Circuit's determination that the Service failed to support its conclusion that whitebark pine declines did not threaten GYE grizzly bears.

On March 11, 2016, we proposed to designate the GYE population of grizzly bears as a DPS and to remove (delist) this DPS from the Federal List of Endangered and Threatened Wildlife (81 FR 13174). In addition, our proposed rule included a notice announcing the availability of the draft Grizzly Bear Recovery Plan Supplement: Revised Demographic Criteria and the draft 2016 Conservation Strategy. The proposed rule was followed by a 60-day comment period, during which we held two open houses and two public hearings (81 FR 13174, March 11, 2016). The public comment period was later reopened for an additional 30 days in light of the receipt of five peer reviews and the States of Idaho, Montana, and Wyoming finalizing regulatory mechanisms to manage human-caused mortality of grizzly bears (81 FR 61658, September 7, 2016). Please refer to the proposed rule for more detailed information on previous Federal actions (81 FR 13174, March 11, 2016).

Background

Grizzly bears (*Ursus arctos horribilis*) are a member of the brown bear species (*U. arctos*) that occurs in North America, Europe, and Asia; the subspecies *U. a. horribilis* is limited to North America (Rausch 1963, p. 43; Servheen 1999, pp. 50–53). Grizzly bears are generally larger than other bears and average 200 to 300 kilograms (kg) (400 to 600 pounds (lb)) for males and 110 to 160 kg (250 to 350 lb) for females in the lower 48 States (Craighead and Mitchell 1982, pp. 517–520; Schwartz *et al.* 2003, p. 558). Although their coloration can vary widely from light brown to nearly black (LeFranc *et al.* 1987, pp. 17–18), they can be distinguished from black bears by longer curved claws, humped shoulders, and a face that appears to be concave (Craighead and Mitchell 1982, p. 517). Grizzly bears are long-lived mammals, generally living to be around 25 years old (LeFranc *et al.* 1987, pp. 47, 51).

Adult grizzly bears are normally solitary except when females have dependent young (Nowak and Paradiso 1983, p. 971), but they are not territorial and home ranges of adult bears frequently overlap (Schwartz *et al.* 2003, pp. 565–566). Home range size is affected by resource availability, sex, age, and reproductive status (LeFranc *et al.* 1987, p. 31; Blanchard and Knight 1991, pp. 48–51; Mace and Waller 1997, p. 48). The annual home ranges of adult male grizzly bears in the GYE are approximately 800 square kilometers (km^2) (309 square miles (mi^2)), while female home ranges are typically smaller, approximately 210 km^2 (81 mi^2) (Bjornlie *et al.* 2014b, p. 3). The large home ranges of grizzly bears, particularly males, enhance maintenance of genetic diversity in the population by enabling males to mate with numerous females (Blanchard and Knight 1991, pp. 46–51; Craighead *et al.* 1998, p. 326).

Grizzly bears are extremely omnivorous, display great diet plasticity—even within a population (Edwards *et al.* 2011, pp. 883–886)—and shift and switch food habits according to their availability (Servheen 1983, pp. 1029–1030; Mace and Jonkel 1986, p. 108; LeFranc *et al.* 1987, pp. 113–114; Aune and Kasworm 1989, pp. 63–71; Schwartz *et al.* 2003, pp. 568–569; Gunther *et al.* 2014, p. 65). Gunther *et al.* (2014, p. 65) conducted an extensive literature review and documented over 260 species of foods consumed by grizzly bears in the GYE, representing 4 of the 5 kingdoms of life. The ability to use whatever food resources are available is one reason grizzly bears are the most widely distributed bear species in the world, occupying habitats from deserts to alpine mountains and everything in between. This ability to live in a variety of habitats and eat a wide array of foods makes grizzly bears a generalist species.

Grizzly bears use a variety of habitats in the GYE (LeFranc *et al.* 1987, p. 120). In general, a grizzly bear's individual habitat needs and daily movements are largely driven by the search for food, mates, cover, security, or den sites. The available habitat for bears is also influenced by people and their activities. Human activities are the primary factor impacting habitat security and the ability of bears to find and access foods, mates, cover, and den sites (Mattson *et al.* 1987, pp. 269–271; McLellan and Shackleton 1988, pp. 458–459; McLellan 1989, pp. 1862–1864; Mace *et al.* 1996, pp. 1402–1403; Nielsen *et al.* 2006, p. 225; Schwartz *et al.* 2010, p. 661). Other factors influencing habitat use and function for grizzly bears include overall habitat productivity (*e.g.,* food distribution and abundance), the availability of habitat components (*e.g.,* denning areas, cover types), grizzly bear social dynamics, learned behavior and preferences of individual grizzly bears, grizzly bear population density, and random variation (LeFranc *et al.* 1987, p. 120).

For detailed information on the biology of this species, see the ''Taxonomy and Species Description, Behavior and Life History, Nutritional Ecology, and Habitat Management'' sections of the March 11, 2016, proposed rule Removing the Greater Yellowstone Ecosystem Population of Grizzly Bears from the Federal List of Endangered and Threatened Wildlife; proposed rule (81 FR 13176–13186).

Population Ecology—Background

The scientific discipline that informs decisions about most wildlife population management is population

ecology: The study of how populations change over time and space and interact with their environment (Vandermeer and Goldberg 2003, p. 2; Snider and Brimlow 2013, p. 1). Ultimately, the goal of population ecology is to understand why and how populations change over time. Wildlife managers and population ecologists monitor a number of factors to gauge the status of a population and make scientifically informed decisions. These measures include population size, population trend, density, and current range.

While population size is a well-known and easily understood metric, it only provides information about a population at a single point in time. Wildlife managers often want to know how a population is changing over time and why. Population trend is determined by births, deaths, and how many animals move into or out of the population (*i.e.,* disperse) and is typically expressed as the population growth rate (represented by the symbol λ, the Greek letter ''lambda''). For grizzly bear populations, lambda estimates the average rate of annual growth, with a value of 1.0 indicating a stable population trend with no net growth or decline. A lambda value of 1.03 means the population size is increasing at 3 percent per year. Conversely, a lambda value of 0.98 means the population size is decreasing at 2 percent per year.

In its simplest form, population trend is driven by births and deaths. Survival and reproduction are the fundamental demographic vital rates driving whether the grizzly bear population increases, decreases, or remains stable. When wildlife biologists refer to demographic vital rates, they are referring to all of the different aspects of reproduction and survival that cumulatively determine a population's trend (*i.e.,* lambda). Some of the demographic factors influencing population trend for grizzly bears are age-specific survival, sex-specific survival, average number of cubs per litter, the time between litters (*i.e.,* interbirth interval), age ratios, sex ratios, average age of first reproduction, lifespan, transition probabilities (see *Glossary*), immigration, and emigration. These data are all used to determine if and why a population is increasing or decreasing (Anderson 2002, p. 53; Mills 2007, p. 59; Mace *et al.* 2012, p. 124).

No population can grow forever because the resources it requires are finite. This understanding led ecologists to develop the concept of carrying capacity (expressed as the symbol ''K''). This is the maximum number of individuals a particular environment can support over the long term without resulting in population declines caused by resource depletion (Vandermeer and Goldberg 2003, p. 261; Krebs 2009, p. 148). Classical studies of population growth occurred under controlled laboratory conditions where populations of a single organism, often an insect species or single-celled organism, were allowed to grow in a confined space with a constant supply of food (Vandermeer and Goldberg 2003, pp. 14–17). Under these conditions, K is a constant value that is approached in a predictable way and can be described by a mathematical equation. However, few studies of wild populations have demonstrated the stability and constant population size suggested by this equation. Instead, many factors affect carrying capacity of animal populations in the wild, and carrying capacity itself typically varies over time. Populations usually fluctuate above and below carrying capacity, resulting in relative population stability over time (*i.e.,* lambda value of approximately 1.0 over the long term) (Colinvaux 1986, pp. 138–139, 142; Krebs 2009, p. 148). For populations at or near carrying capacity, population size may fluctuate just above and below carrying capacity around a long-term mean, sometimes resulting in annual estimates of lambda showing a declining population (figure 2). However, to obtain a biologically meaningful estimate of average annual population growth rate for a long-lived species like the grizzly bear that reproduces only once every 3 years and does not start reproducing until at least 4 years old, we must examine lambda over a longer period of time to see what the average trend is over that specified time. This is not an easy task. For grizzly bears, it takes at least 6 years of monitoring as many as 30 females with radio-collars to accurately estimate average annual population growth (Harris *et al.* 2011, p. 29).

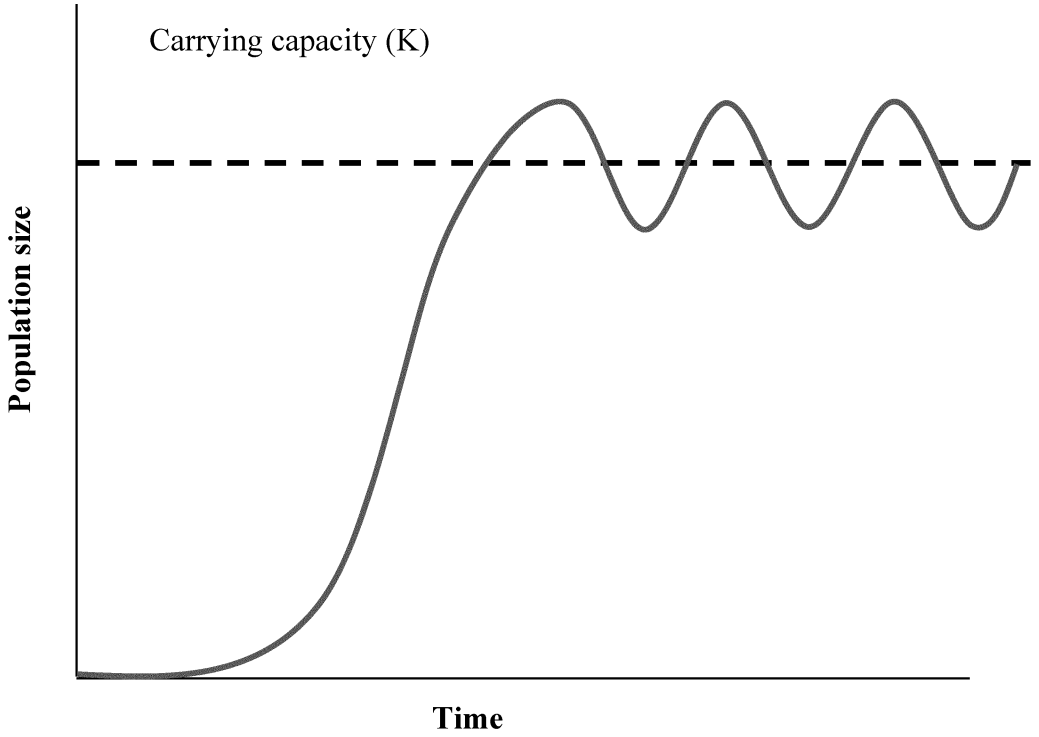

Figure 2. Typical population trend with respect to carrying capacity (K). When the population is low, growth rate is rapid. When the population is at or near K, growth rates decelerate and may temporarily decrease as population size fluctuates around K. This figure has been edited to show that fluctuations are typically larger than what was depicted in the proposed rule.

When a population is at or near carrying capacity, mechanisms that regulate or control population size fall into two broad categories: Density-dependent effects and density-independent effects. Generally, factors that limit population growth more strongly as population size increases are density-dependent effects, or intrinsic factors, usually expressed through individual behaviors, physiology, or genetic potential (McLellan 1994, p. 15). Extrinsic factors, such as drought or fire that kill individuals regardless of how many individuals are in a population, are considered density-independent effects (Colinvaux 1986, p. 172). These extrinsic factors may include changes in resources, predators, or human impacts and may cause carrying capacity to vary over time. Population stability (*i.e.,* fluctuation around carrying capacity or a long-term equilibrium) is often influenced by a combination of density-dependent and density-independent effects. Among grizzly bears, indicators of density-dependent population regulation can include: (1) Decreased yearling and cub survival due to increases in intraspecific killing (*i.e.,* bears killing other bears), (2) decreases in home range size, (3) increases in generation time, (4) increases in age of first reproduction, and (5) decreased reproduction (McLellan 1994, entire; Eberhardt 2002, pp. 2851–2852; Kamath *et al.* 2015, p. 5516; van Manen *et al.* 2016, pp. 307–308). Indicators that density-independent effects are influencing population growth can include: (1) Larger home range sizes (because bears are roaming more widely in search of foods) (McLoughlin *et al.* 2000, pp. 49–51), (2) decreased cub and yearling survival due to starvation, (3) increases in age of first reproduction due to limited food resources, and (4) decreased reproduction due to limited food resources.

As a result of these sometimes similar indicators, determining whether a population is affected more strongly by density-dependent or density-independent effects can be a complex undertaking. For long-lived mammals such as grizzly bears, extensive data collected over decades are needed to understand if and how these factors are operating in a population. We have these data for the GYE grizzly bear population, and the IGBST examined some of these confounding effects to find that density-dependent effects are the likely cause of the recent slowing in population growth factors. The slowing of population growth since the early 2000s was primarily a function of lower survival of dependent young and moderate reproductive suppression (IGBST 2012, p. 8). Survival of cubs-of-the-year and reproduction were lower in areas with higher grizzly bear densities but showed no association with estimates of decline in whitebark pine tree cover, suggesting that density-dependent factors contributed to the change in population growth (van Manen *et al.* 2016, entire). In addition, female home range sizes have decreased in areas of greater bear densities, as would be expected if density-dependent regulation is occurring (Bjornlie *et al.* 2014b, p. 4) (see *Changes in Food Resources* under *Factor E,* below, for more detailed information).

Population viability analyses (PVAs) are another tool population ecologists often use to assess the status of a population by estimating its likelihood of persistence in the future. Boyce *et al.*

(2001, pp. 1–11) reviewed the existing published PVAs for GYE grizzly bears and updated these previous analyses using data collected since the original analyses were completed. They also conducted new PVAs using two software packages that had not been available to previous investigators. They found that the GYE grizzly bear population had a 1 percent chance of going extinct within the next 100 years and a 4 percent chance of going extinct in the next 500 years (Boyce *et al.* 2001, pp. 1, 10–11). The authors cautioned that their analyses were not entirely sufficient because they were not able to consider possible changes in habitat and how these may affect population vital rates (Boyce *et al.* 2001, pp. 31–32). Based on the recommendation that the population models incorporate habitat variables, Boyce worked with other researchers to develop a habitat-based framework for evaluating mortality risk of a grizzly bear population in Alberta, Canada (Nielsen *et al.* 2006, p. 225). They concluded that secure habitat (low mortality risk) was the key to grizzly bear survival. Schwartz *et al.* (2010, p. 661) created a similar mortality risk model for the GYE with similar results. Both studies suggest that managing for secure habitat is one of the most effective management actions to ensure population persistence.

Recovery Planning and Implementation

Background

Prior to the arrival of Europeans, the grizzly bear occurred throughout the western half of the contiguous United States, central Mexico, western Canada, and most of Alaska (Roosevelt 1907, pp. 27–28; Wright 1909, pp. vii, 3, 185–186; Merriam 1922, p. 1; Storer and Tevis 1955, p. 18; Rausch 1963, p. 35; Herrero 1972, pp. 224–227; Schwartz *et al.* 2003, pp. 557–558). Pre-settlement population levels for the western contiguous United States are believed to have been in the range of 50,000 animals (Servheen 1999, p. 50). With European settlement of the American West and government-funded bounty programs aimed at eradication, grizzly bears were shot, poisoned, and trapped wherever they were found, and the resulting declines in range and population were dramatic (Roosevelt 1907, pp. 27–28; Wright 1909, p. vii; Storer and Tevis 1955, pp. 26–27; Leopold 1967, p. 30; Koford 1969, p. 95; Craighead and Mitchell 1982, p. 516; Servheen 1999, pp. 50–51). The range and numbers of grizzly bears were reduced to less than 2 percent of their former range and numbers by the 1930s, approximately 125 years after first contact with European settlers (USFWS 1993, p. 9; Servheen 1999, p. 51). Of 37 grizzly bear populations present within the lower 48 States in 1922, 31 were extirpated by 1975 (Servheen 1999, p. 51).

By the 1950s, with little or no conservation effort or management directed at maintaining grizzly bears anywhere in their range, the GYE population had been reduced in numbers and was restricted largely to the confines of YNP and some surrounding areas (Craighead *et al.* 1995, pp. 41–42; Schwartz *et al.* 2003, pp. 575–579). High grizzly bear mortality in 1970 and 1971, following closure of the open-pit garbage dumps in YNP (Gunther 1994, p. 550; Craighead *et al.* 1995, pp. 34–36), and concern about grizzly bear population status throughout its remaining range prompted the 1975 listing of the grizzly bear as a threatened species in the lower 48 States under the Act (40 FR 31734, July 28, 1975). When the grizzly bear was listed in 1975, the population estimate in the GYE ranged from 136 to 312 individuals (Cowan *et al.* 1974, pp. 32, 36; Craighead *et al.* 1974, p. 16; McCullough 1981, p. 175).

Grizzly bear recovery has required, and will continue to require, cooperation among numerous government agencies and the public for a unified management approach. To this end, there are three interagency groups that help guide grizzly bear management in the GYE. The IGBST, created in 1973, provides the scientific information necessary to make informed management decisions about grizzly bear habitat and conservation in the GYE. Since its formation in 1973, the published work of the IGBST has made the GYE grizzly bear population the most studied in the world. The wealth of biological information produced by the IGBST over the years includes 30 annual reports, hundreds of articles in peer-reviewed journals, dozens of theses, and other technical reports (see: *https://www.usgs.gov/science/interagency-grizzly-bear-study-team?qt-science_center_objects=4#qt-science_center_objects*). Members of the IGBST include scientists and wildlife managers from the Service, U.S. Geological Survey (USGS), National Park Service (NPS), U.S. Forest Service (USFS), academia, and each State wildlife agency involved in grizzly bear recovery.

The second interagency group guiding grizzly bear conservation efforts is the Interagency Grizzly Bear Committee (IGBC). Created in 1983, its members coordinate management efforts and research actions across multiple Federal lands and States to recover the grizzly bear in the lower 48 States (USDA and USDOI 1983, entire). One of the objectives of the IGBC is to change land management practices to more effectively provide security and maintain or improve habitat conditions for the grizzly bear (USDA and USDOI 1983, entire). IGBC members include upper level managers from the Service, USFS, USGS, Bureau of Land Management (BLM), and the States of Idaho, Montana, Washington, and Wyoming (USDA and USDOI 1983, entire). The IGBST Team Leader, the National Carnivore Program Leader, and the Service Grizzly Bear Recovery Coordinator are advisors to the subcommittee providing all the scientific information on the GYE grizzly bear population and its habitat.

The third interagency group guiding management of the GYE grizzly bear is a subcommittee of the IGBC: The Yellowstone Ecosystem Subcommittee (YES). Formed in 1983 to coordinate recovery efforts specific to the GYE, the YES includes mid-level managers and representatives from the Service; the five GYE National Forests (the Shoshone, Beaverhead-Deerlodge, Bridger-Teton, Custer Gallatin, and Caribou-Targhee); YNP; GTNP; the Wyoming Game and Fish Department (WGFD); the Montana Department of Fish, Wildlife, and Parks (MFWP); the Idaho Department of Fish and Game (IDFG); the BLM; county governments from each affected State; and the Shoshone Bannock, Northern Arapahoe, and Eastern Shoshone Tribes (USDA and USDOI 1983). The IGBST Team Leader and the Service Grizzly Bear Recovery Coordinator are advisors to the subcommittee providing all the scientific information on the GYE grizzly bear population and its habitat. Upon implementation of the 2016 Conservation Strategy, the Yellowstone Grizzly Bear Coordinating Committee (YGCC) will replace the YES.

Recovery Planning

In accordance with section 4(f)(1) of the Act, the Service completed a Grizzly Bear Recovery Plan (Recovery Plan) in 1982 (USFWS 1982, p. ii). Recovery plans serve as road maps for species recovery—they lay out where we need to go and how to get there through specific actions. Recovery plans are not regulatory documents and are instead intended to provide guidance to the Service, States, and other partners on methods of minimizing threats to listed species and on criteria that may be used to determine when recovery is achieved.

The Recovery Plan identified six recovery ecosystems within the conterminous United States thought to support grizzly bears. Today, current

grizzly bear distribution is primarily within and around the areas identified as Recovery Zones (USFWS 1993, pp. 10–13, 17–18), including: (1) The GYE in northwestern Wyoming, eastern Idaho, and southwestern Montana (24,000 km² (9,200 mi²)) at more than 700 bears (Haroldson *et al.* 2014, p. 17); (2) the Northern Continental Divide Ecosystem (NCDE) of north-central Montana (25,000 km² (9,600 mi²)) at more than 900 bears (Kendall *et al.* 2009, p. 9; Mace *et al.* 2012, p. 124); (3) the North Cascades area of north-central Washington (25,000 km² (9,500 mi²)) at fewer than 20 bears (last documented sighting in 1996) (Almack *et al.* 1993, p. 4; NPS and USFWS 2015, p. 3); (4) the Selkirk Mountains area of northern Idaho, northeastern Washington, and southeastern British Columbia (5,700 km² (2,200 mi²)) at approximately 88 bears (USFWS 2011, p. 26); and (5) the Cabinet-Yaak area of northwestern Montana and northern Idaho (6,700 km² (2,600 mi²)) at approximately 48 bears (Kendall *et al.* 2016, p. 314). The Bitterroot Ecosystem in the Bitterroot Mountains of central Idaho and western Montana (14,500 km² (5,600 mi²)) is not known to contain a population of grizzly bears at this time (USFWS 1996, p. 1; 65 FR 69624, November 17, 2000; USFWS 2000, pp. 1–3). The San Juan Mountains of Colorado also were identified as an area of possible grizzly bear occurrence (40 FR 31734, July 28, 1975; USFWS 1982, p. 12; USFWS 1993, p. 11), but no confirmed sightings of grizzly bears have occurred there since a grizzly bear mortality in 1979 (USFWS 1993, p. 11).

In 1993, the Service completed revisions to the Recovery Plan to include additional tasks and new information that increased the focus and effectiveness of recovery efforts (USFWS 1993, pp. 41–58). In 1996 and 1997, we released supplemental chapters to the Recovery Plan to direct recovery in the Bitterroot and North Cascades Recovery Zones, respectively (USFWS 1996; USFWS 1997). In the GYE, we updated both the habitat and demographic recovery criteria in 2007 (72 FR 11376, March 13, 2007). We proposed revisions to the demographic recovery criteria in 2013 (78 FR 17708, March 22, 2013) and proposed additional revisions concurrent with the proposed rule (81 FR 13174, March 11, 2016) to reflect the best available science. Although it is not necessary to update recovery plans prior to delisting, the *Recovery Plan Supplement: Revised Demographic Recovery Criteria* was updated to reflect the best available science because the 2016 Conservation Strategy directly incorporates the Recovery Plan for post-delisting monitoring. The final revised demographic recovery criteria are appended to the Recovery Plan concurrent with this final rule. Below, we report the status of both the habitat and demographic recovery criteria in the GYE.

In 1979, the IGBST developed the first comprehensive ''Guidelines for Management Involving Grizzly Bears in the Greater Yellowstone Area'' (hereafter referred to as the Guidelines) (Mealey 1979, pp. 1–4). We determined in a biological opinion that implementation of the Guidelines by Federal land management agencies would promote conservation of the grizzly bear (USFWS 1979, p. 1). Beginning in 1979, the five affected National Forests (Beaverhead-Deerlodge, Bridger-Teton, Caribou-Targhee, Custer Gallatin, and Shoshone), YNP and GTNP, and the BLM in the GYE began managing habitats for grizzly bears under direction specified in the Guidelines.

In 1986, the IGBC modified the Guidelines to more effectively manage habitat by mapping and managing according to three different management situations (USDA FS 1986, pp. 35–39). In areas governed by ''Management Situation One,'' grizzly bear habitat maintenance and improvement and grizzly bear-human conflict minimization received the highest management priority. In areas governed by ''Management Situation Two,'' grizzly bear use was important, but not the primary use of the area. In areas governed by ''Management Situation Three,'' grizzly bear habitat maintenance and improvement were not management considerations.

The National Forests and National Parks delineated 18 different bear management units (BMUs) within the GYE Recovery Zone to aid in managing habitat and monitoring population trends. Each BMU was further subdivided into subunits, resulting in a total of 40 subunits contained within the 18 BMUs (see map at *http://www.fws.gov/mountain-prairie/es/species/mammals/grizzly/Yellowstone_Recovery_Zone_map.pdf*). The BMUs are analysis areas that approximate the lifetime size of a female's home range, while subunits are analysis areas that approximate the annual home range size of adult females. Subunits provide the optimal scale for evaluation of seasonal feeding opportunities and landscape patterns of food availability for grizzly bears (Weaver *et al.* 1986, p. 236). The BMUs and subunits were identified to provide enough quality habitat and to ensure that grizzly bears were well distributed across the GYE Recovery Zone as per the Recovery Plan (USFWS 2007*c,* pp. 20, 41, 44–46). Management improvements made as a result of these Guidelines are discussed under *Factor A,* below.

Habitat-Based Recovery Criteria

On June 17, 1997, we held a public workshop in Bozeman, Montana, to develop and refine habitat-based recovery criteria for the grizzly bear, with an emphasis on the GYE. This workshop was held as part of the settlement agreement in *Fund for Animals* v. *Babbitt,* 967 F.Supp.6 (D. D.C. 1997). A **Federal Register** notice notified the public of this workshop and provided interested parties an opportunity to participate and submit comments (62 FR 19777, April 23, 1997). After considering 1,167 written comments, we developed biologically based habitat recovery criteria, which were appended to the 1993 Recovery Plan in 2007 (USFWS 2007*b,* entire), with the overall goal of maintaining or improving habitat conditions at levels that existed in 1998.

There is no published method to deductively calculate minimum habitat values required for a healthy and recovered population. Grizzly bears are long-lived opportunistic omnivores whose food and space requirements vary depending on a multitude of environmental and behavioral factors and on variation in the experience and knowledge of each individual bear. Grizzly bear home ranges overlap and change seasonally, annually, and with reproductive status. While these factors make the development of threshold habitat criteria difficult, these may be established by assessing what habitat factors in the past were compatible with a stable to increasing grizzly bear population, and then using these habitat conditions as threshold values to be maintained to ensure a healthy population (*i.e.,* a ''no net loss'' approach), as suggested by Nielsen *et al.* (2006, p. 227). We selected 1998 levels as our baseline year because it was known that habitat values at that time were compatible with an increasing grizzly bear population throughout the 1990s (Harris *et al.* 2006, p. 48) and that the levels of both secure habitat and the number and capacity of developed sites (those sites or facilities on federal public land with features intended to accommodate public use or recreation) had changed little from 1988 to 1998 (USDA FS 2004, pp. 140–141, 159–162). The 1998 baseline is also described in detail in *Factor A,* below.

The habitat-based recovery criteria established objective, measurable values

for levels of motorized access, secure habitat, developed sites, and livestock allotments (*i.e.,* ''the 1998 baseline'') for the GYE. The 1998 values will not change through time, unless improvements benefit bears (*e.g.,* expansion of existing administrative sites to enhance public land management if other viable alternatives are not available, modifications to dispersed or developed sites to reduce grizzly bear conflicts, such as installing bear-resistant storage structures). As each of these management objectives are central to potential present or threatened destruction, modification, or curtailment of habitat or range, they are discussed in detail under *Factor A,* below. These habitat-based recovery criteria have been met since their incorporation into the Recovery Plan (USFWS 2007*b,* entire).

Additionally, we developed several monitoring items that may help inform management decisions or explain population trends: (1) Trends in the location and availability of food sources such as whitebark pine (*Pinus albicaulis*), cutthroat trout (*Oncorhynchus clarki*), army cutworm moths (*Euxoa auxiliaris*), and ungulates (bison (*Bison bison*) and elk (*Cervus canadensis*)); and (2) grizzly bear mortality numbers, locations, and causes; grizzly bear-human conflicts; conflict bear management actions; bear-hunter conflicts; and bear-livestock conflicts (YES 2016a, pp. 33–91). Federal and State agencies monitor these items, and the IGBST produces an annual report with their results. This information is used to examine relationships between food availability, human activity, and demographic parameters of the population such as survival, population growth, or reproduction. The habitat-based recovery criteria were appended to the Recovery Plan in 2007 and are included in the 2016 Conservation Strategy, which is the comprehensive post-delisting management plan for a recovered population as called for in the Recovery Plan.

Suitable Habitat

Because we used easily recognized boundaries to delineate the boundaries of the GYE grizzly bear DPS, it includes both suitable and unsuitable habitat (figure 1). For the purposes of this final rule, ''suitable habitat'' is considered the area within the DPS boundaries capable of supporting grizzly bear reproduction and survival now and in the foreseeable future. We have defined ''suitable habitat'' for grizzly bears as areas having three characteristics: (1) Being of adequate habitat quality and quantity to support grizzly bear reproduction and survival; (2) being contiguous with the current distribution of GYE grizzly bears such that natural recolonization is possible; and (3) having low mortality risk as indicated through reasonable and manageable levels of grizzly bear mortality.

Our definition and delineation of suitable habitat is built on the widely accepted conclusions of extensive research (Craighead 1980, pp. 8–11; Knight 1980, pp. 1–3; Peek *et al.* 1987, pp. 160–161; Merrill *et al.* 1999, pp. 233–235; Schwartz *et al.* 2010, p. 661) that grizzly bear reproduction and survival is a function of both the biological needs of grizzly bears and remoteness from human activities, which minimizes mortality risk for grizzly bears. Mountainous areas provide hiding cover, the topographic variation necessary to ensure a wide variety of seasonal foods, and the steep slopes used for denning (Judd *et al.* 1986, pp. 114–115; Aune and Kasworm 1989, pp. 29–58; Linnell *et al.* 2000, pp. 403–405). Higher elevation, mountainous regions in the GYE (Omernik 1987, pp. 118–125; Omernik 1995, pp. 49–62; Woods *et al.* 1999, entire; McGrath *et al.* 2002, entire; Chapman *et al.* 2004, entire) contain high-energy foods such as whitebark pine seeds (Mattson and Jonkel 1990, p. 223; Mattson *et al.* 1991*a,* p. 1623) and army cutworm moths (Mattson *et al.* 1991*b,* 2434; French *et al.* 1994, p. 391).

For our analysis of suitable habitat, we considered the Middle Rockies ecoregion, within which the GYE is contained (Omernik 1987, pp. 120–121; Woods *et al.* 1999, entire; McGrath *et al.* 2002, entire; Chapman *et al.* 2004, entire), to meet grizzly bear biological needs providing food, seasonal foraging opportunities, cover, and denning areas (Mattson and Merrill 2002, p. 1125). Although grizzly bears historically occurred throughout the area of the proposed GYE grizzly bear DPS (Stebler 1972, pp. 297–298), today many of these habitats are not biologically suitable for grizzly bears. While there are records of grizzly bears in eastern Wyoming near present-day Sheridan, Casper, and Wheatland, even in the early 19th century, indirect evidence suggests that grizzly bears were less common in these eastern prairie habitats than in mountainous areas to the west (Rollins 1935, p. 191; Wade 1947, p. 444).

Grizzly bear presence in these drier, grassland habitats was associated with rivers and streams where grizzly bears used bison carcasses as a major food source (Burroughs 1961, pp. 57–60; Herrero 1972, pp. 224–227; Stebler 1972, pp. 297–298; Mattson and Merrill 2002, pp. 1128–1129). Most of the short-grass prairie on the east side of the Rocky Mountains has been converted into agricultural land (Woods *et al.* 1999, entire), and high densities of traditional food sources are no longer available due to land conversion and human occupancy of urban and rural lands. Traditional food sources such as bison and elk have been reduced and replaced with domestic livestock such as cattle, sheep, chickens, goats, pigs, and bee hives, which can become anthropogenic sources of prey for grizzly bears. While food sources such as grasses and berries are abundant in some years in the riparian zones within which the bears travel, these are not reliable every year and can only support a small number of bears. These nutritional constraints and the potential for human-bear conflicts limit the potential for a self-sustaining population of grizzly bears to develop in the prairies, although we expect some grizzly bears to live in these areas. Because wild bison herds no longer exist in these areas, and are mainly contained within YNP in the GYE, they are no longer capable of contributing in a meaningful way to the overall status of the GYE grizzly bear DPS. Thus, we did not include drier sagebrush, prairie, or agricultural lands within our definition of suitable habitat because these land types no longer contain adequate food resources (*i.e.,* bison) to support grizzly bears. Figure 1 illustrates suitable habitat within the GYE grizzly bear DPS.

Although there are historical records of grizzly bears throughout the GYE DPS, evidence suggests that grizzly bears were less common in prairie habitats (Rollins 1935, p. 191; Wade 1947, p. 444). Bears in these peripheral areas will not establish self-sustaining, year-round populations due to a lack of suitable habitat, land ownership patterns, and the lack of traditional, natural grizzly bear foods (*i.e.,* bison). Instead, bears in these peripheral areas will likely always rely on the GYE grizzly bear population inside the DMA as a source population. Grizzly bears in these peripheral areas are not biologically necessary to the GYE grizzly bear population and a lack of occupancy outside the DMA boundaries in peripheral areas will not impact whether the GYE population is likely to become endangered or threatened in the foreseeable future throughout all or a significant portion of its range. Grizzly bear recovery in these portions of the species' historical range is unnecessary, because there is more than enough suitable habitat to support a viable and

recovered grizzly bear population as set forth in the demographic recovery criteria. Therefore, additional recovery efforts in these areas are beyond what is required by the Act.

Human-caused mortality risk also can impact which habitat might be considered suitable. Some human-caused mortality is unavoidable in a dynamic system where hundreds of bears inhabit large areas of diverse habitat with several million human visitors and residents. The negative impacts of humans on grizzly bear survival and habitat use are well documented (Harding and Nagy 1980, p. 278; McLellan and Shackleton 1988, pp. 458–459; Aune and Kasworm 1989, pp. 83–103; McLellan 1989, pp. 1862–1864; McLellan and Shackleton 1989, pp. 377–378; Mattson 1990, pp. 41–44; Mattson and Knight 1991, pp. 9–11; Mace *et al.* 1996, p. 1403; McLellan *et al.* 1999, pp. 914–916; White *et al.* 1999, p. 150; Woodroffe 2000, pp. 166–168; Boyce *et al.* 2001, p. 34; Johnson *et al.* 2004, p. 976; Schwartz *et al.* 2010, p. 661). These effects range from temporary displacement to actual mortality. Grizzly bear persistence in the contiguous United States between 1920 and 2000 was negatively associated with human and livestock densities (Mattson and Merrill 2002, pp. 1129–1134).

As human population densities increase, the frequency of encounters between humans and grizzly bears also increases, resulting in more human-caused grizzly bear mortalities due to a perceived or real threat to human life or property (Mattson *et al.* 1996, pp. 1014–1015). Similarly, as livestock densities increase in habitat occupied by grizzly bears, depredations follow. Although grizzly bears frequently coexist with cattle without depredating them, when grizzly bears encounter domestic sheep, they usually are attracted to such flocks and depredate the sheep (Jonkel 1980, p. 12; Knight and Judd 1983, pp. 188–189; Orme and Williams 1986, pp. 199–202; Anderson *et al.* 2002, pp. 252–253). If repeated depredations occur, managers either relocate the bear or remove it (*i.e.,* euthanize or place in an approved American Zoological Association facility) from the population, resulting in such domestic sheep areas becoming population sinks (areas where death rates exceed birth rates) (Knight *et al.* 1988, pp. 122–123).

Because urban sites and sheep allotments possess high mortality risks for grizzly bears, we did not include these areas as suitable habitat (Knight *et al.* 1988, pp. 122–123). Based on 2000 census data, we defined urban areas as census blocks with human population densities of more than 50 people per km^2 (129 people per mi^2) (U.S. Census Bureau 2005, entire). Cities within the Middle Rockies ecoregion, such as West Yellowstone, Gardiner, Big Sky, and Cooke City, Montana, and Jackson, Wyoming, were not included as suitable habitat. There are large, contiguous blocks of sheep allotments in peripheral areas of the ecosystem in the Wyoming Mountain Range, the Salt River Mountain Range, and portions of the Wind River Mountain Range on the Bridger-Teton and the Targhee National Forests (see figure 1). This spatial distribution of sheep allotments on the periphery of suitable habitat results in areas of high mortality risk to bears within these allotments and a few small, isolated patches or strips of suitable habitat adjacent to or within sheep allotments. These strips and patches of land possess higher mortality risks for grizzly bears because of their enclosure by and/or proximity to areas of high mortality risk. This phenomenon in which the quantity and quality of suitable habitat is diminished because of interactions with surrounding less suitable habitat is known as an ''edge effect'' (Lande 1988, pp. 3–4; Yahner 1988, pp. 335–337; Mills 1995, p. 396). Edge effects are exacerbated in small habitat patches with high perimeter-to-area ratios (*i.e.,* those that are longer and narrower) and in wide-ranging species such as grizzly bears because they are more likely to encounter surrounding, unsuitable habitat (Woodroffe and Ginsberg 1998, p. 2126). Due to the negative edge effects of this distribution of sheep allotments on the periphery of current grizzly bear range, our analysis did not classify linear strips and isolated patches of habitat as suitable habitat.

Finally, dispersal capabilities of grizzly bears were considered in our determination of which potential habitat areas might be considered suitable. Although the Bighorn Mountains west of I–90 near Sheridan, Wyoming, are grouped within the Middle Rockies ecoregion, they are not connected to the current distribution of grizzly bears via suitable habitat or linkage zones, nor are there opportunities for such linkage. The Bighorn Mountains comprise 6,341 km^2 (2,448 mi^2) of habitat that is classified as part of the Middle Rockies ecoregion, but are separated from the current grizzly bear distribution by approximately 100 km (60 mi) of a mosaic of private and BLM lands primarily used for agriculture, livestock grazing, and oil and gas production (Chapman *et al.* 2004, entire). Although there is a possibility that individual bears may emigrate from the GYE to the Bighorn Mountains occasionally, this dispersal distance exceeds the average dispersal distance for both males (30 to 42 km (19 to 26 mi)) and females (10 to 14 km (6 to 9 mi)) (McLellan and Hovey 2001, p. 842; Proctor *et al.* 2004, p. 1108). Without constant emigrants from suitable habitat, the Bighorn Mountains will not support a self-sustaining grizzly bear population. Therefore, due to the fact that this mountain range is disjunct from other suitable habitat and current grizzly bear distribution, our analysis did not classify the Bighorn Mountains as suitable habitat within the GYE grizzly bear DPS boundaries.

Some areas that do not meet our definition of suitable habitat may still be used by grizzly bears (4,635 km^2 (1,787 mi^2)) (Schwartz *et al.* 2002, p. 209; Schwartz *et al.* 2006b, pp. 64–66). The records of grizzly bears in these unsuitable habitat areas are generally due to recorded grizzly bear-human conflicts or to transient animals. These areas are defined as unsuitable due to the high risk of mortality resulting from these grizzly bear-human conflicts. These unsuitable habitat areas may contain grizzly bears but do not support grizzly bear reproduction or survival because bears that repeatedly come into conflict with humans or livestock are usually either relocated or removed from these areas.

According to the habitat suitability criteria described above, the GYE contains approximately 46,035 km^2 (17,774 mi^2) of suitable grizzly bear habitat within the DPS boundaries; or roughly 24 percent of the total area within the DPS boundaries (see figure 1). The Service concluded that this amount of suitable habitat is sufficient to meet all habitat needs of a recovered grizzly bear population and provide ecological resiliency to the population through the availability of widely distributed, high-quality habitat that will allow the population to respond to environmental changes. This amount of secure habitat was chosen because it existed at the time when the population was increasing at a rate of 4 to 7 percent per year (Schwartz *et al.* 2006b, p. 48). Grizzly bears currently occupy about 92 percent of that suitable habitat (42,180 km^2 (16,286 mi^2)) (Fortin-Noreus 2015, *in litt.*) and are expected to occupy the remaining 8 percent in the near future. Grizzly bears have nearly doubled their occupied range since the early 1980s (USFWS 1982, p. 11) and have increased the amount of suitable habitat from the 68 percent that was occupied in the early 2000s (Schwartz *et al.* 2002, pp. 207–209; Schwartz *et al.* 2006b, pp. 64–66). It is important to note that the

current grizzly bear occupancy does not mean that equal densities of grizzly bears are found throughout the region. Instead, most grizzly bears (approximately 75 percent of females with cubs-of-the-year) are within the PCA for most or part of each year (Schwartz *et al.* 2006a, pp. 64–66; Haroldson 2014a, *in litt.*). Grizzly bear use of suitable habitat may vary seasonally and annually with different areas being more important than others in some seasons or years (Aune and Kasworm 1989, pp. 48–62). As predicted by Pyare *et al.* (2004, pp. 5–6), grizzly bears have naturally recolonized the vast majority of suitable habitat and currently occupy about 92 percent of suitable habitat (42,180 km^2 (16,286 mi^2)) (Fortin-Noreus 2015, *in litt.*).

Demographic Recovery Criteria

The 1993 Recovery Plan and subsequent supplements to it identified three demographic criteria to objectively measure and monitor recovery in the GYE (USFWS 1993, pp. 20–21; USFWS 2007*a,* p. 2). The first criterion established a minimum population size. The second criterion ensured reproductive females were distributed across the Recovery Zone, and the third criterion created annual human-caused mortality limits that would allow the population to achieve and sustain recovery. Since the 1993 Recovery Plan was released, we have evaluated and updated how we assess those recovery criteria as newer, better science became available. These revisions include implementing new scientific methods to determine the status of the GYE grizzly bear population in the DMA, estimate population size, and determine what levels of mortality the population could withstand to maintain recovery goals (*i.e.,* the sustainable mortality rate). The DMA is the area within which the population is annually surveyed and estimated and within which the total mortality limits apply, and is based on the suitable habitat area (see figure 2). The Wildlife Monograph: ''Temporal, Spatial, and Environmental Influences on The Demographics of Grizzly Bears in The Greater Yellowstone Ecosystem'' (Schwartz *et al.* 2006b, entire); the report: ''Reassessing Methods to Estimate Population Size and Sustainable Mortality Limits for the Yellowstone Grizzly Bear'' (IGBST 2005, entire); and the report: ''Reassessing Methods to Estimate Population Size and Sustainable Mortality Limits for the Yellowstone Grizzly Bear Workshop Document Supplement 19–21 June, 2006'' (IGBST 2006, entire) provided the scientific basis for revising the demographic recovery criteria in the GYE in 2007 (72 FR 11376, March 13, 2007). Similarly, the revisions we proposed to implement in 2013 (78 FR 17708, March 22, 2013) were based on updated demographic analyses using the same methods as before (Schwartz *et al.* 2006b, pp. 9–16) and reported in the IGBST's 2012 report: ''Updating and Evaluating Approaches to Estimate Population Size and Sustainable Mortality Limits for Grizzly Bears in the Greater Yellowstone Ecosystem'' (hereafter referred to as the 2012 IGBST report).

In 2013, we proposed to change two of the recovery criteria for the Yellowstone Ecosystem in the Grizzly Bear Recovery Plan (78 FR 17708, March 22, 2013). The proposed changes were: (1) Update demographic recovery criterion 1 to maintain a minimum population of 500 animals and at least 48 females with cubs-of-the-year, and to eliminate this criterion's dependence on a specific counting method; (2) revise the area where the demographic recovery criteria apply; and (3) update the sustainable mortality rates for independent females to 7.6 percent (IGBST 2012). We chose to revise the criteria because they no longer represented the best scientific data or the best technique to assess recovery of the GYE grizzly bear DMA population (78 FR 17708, March 22, 2013). Specifically, these criteria warranted revision because: (1) Updated demographic analyses for 2002–2011 indicated that the rate of growth seen during the 1983–2001 period has slowed and sex ratios have changed; (2) there was consensus among scientists and statisticians that the area within which we apply total mortality limits should be the same area we use to estimate population size; and (3) the population had basically stabilized inside the DMA since 2002, with an average population size between 2002–2014 of 674 using the model-averaged Chao2 population estimator (see *Glossary*) (95% confidence interval (CI) = 600–747). This stabilization is evidence that the population was close to its carrying capacity as supported by density-dependent regulation occurring inside the DMA (van Manen *et al.* 2016, entire).

We released these proposed revisions related to population size and total mortality limits for public comment in 2013 (78 FR 17708, March 22, 2013) but did not finalize them so that we could consider another round of public comments on these revisions in association with the comments on the proposed rule (81 FR 13174, March 11, 2016). Further proposed revisions to the Recovery Plan Supplement: Revised Demographic Criteria and the draft 2016 Conservation Strategy for the Grizzly Bear in the GYE were made available for public review and comment concurrent with the proposed rule (81 FR 13174, March 11, 2016). The first two proposed changes were the same as those proposed in 2013: (1) Update demographic recovery criterion 1 to maintain a minimum population of 500 animals and at least 48 females with cubs-of-the-year, and to eliminate this criterion's dependence on a specific counting method; and (2) revise the area where the demographic recovery criteria apply. The third change is to update the mortality limits for independent females, independent males, and dependent young to maintain the population within the DMA around the 2002–2014 population size. After review and incorporation of appropriate public comments, we are releasing a final Grizzly Bear Recovery Plan Supplement: Revised Demographic Criteria (USFWS 2017, entire) and announcing the availability of the 2016 Conservation Strategy for the Grizzly Bear in the GYE concurrent with this final rule.

Below, we summarize relevant portions of the demographic analyses contained in the IGBST's 2012 report (IGBST 2012, entire) and compare them with the previous results of Schwartz *et al.* (2006b, entire) to draw conclusions concerning the grizzly bear population in the GYE DMA using these collective results. These analyses inform the scientific basis for our revisions. While Schwartz *et al.* (2006b, p. 11) used data from 1983 through 2001; the 2012 IGBST report examined a more recent time period, 2002 through 2011 (IGBST 2012, p. 33). The IGBST found that population growth had slowed since the previous time period, but was still stable to slightly increasing, meaning the population had not declined. Because the fates of some radio-collared bears are unknown, Harris *et al.* (2006, p. 48) and the IGBST (2012, p. 34) calculated two separate estimates of population growth rate: One based on the assumption that every bear with an unknown fate had died (*i.e.,* a conservative estimate) and the other simply removing bears with an unknown fate from the sample. The true population growth rate is assumed to be somewhere in between these two estimates because we know from 40 years of tracking grizzly bears with radio-collars that every lost collar does not indicate a dead bear. While Harris *et al.* (2006, p. 48) found the GYE grizzly bear DMA population increased at a rate between 4.2 and 7.6 percent per year

between 1983 and 2002, the IGBST (2012, p. 34) found this growth had slowed and leveled off and was between 0.3 percent and 2.2 percent per year during 2002–2011. The population trajectory that includes the most recent data is based on the Chao2 estimator and indicates no statistical trend (*i.e.,* relatively flat population trajectory) within the DMA for the period 2002 to 2014 (van Manen 2016a, *in litt.*).

The model-averaged Chao2 population estimator is currently the best available science to derive annual estimates of total population size in the GYE. The basis for the estimation is an annual count of female grizzly bears with cubs-of-the-year, based on sightings on aerial surveys and ground observations. Those sightings are clustered into those estimated to be from the same family group (*i.e.,* female with cubs-of-the-year) using a ''rule set'' to avoid duplicate counts, primarily based on spatial, temporal, and litter size criteria (Knight *et al.* 1995). In clustering the observations, a balance must be obtained between overestimating or underestimating the actual number of unique females with cubs-of-the-year. The rule set was constructed to be conservative (*i.e.,* reduce Type I errors or mistakenly identifying sightings of the same family as different families). Using the frequencies of sightings of unique females with cubs-of-the-year obtained from application of the rule set, an annual estimate of the total number of females with cubs-of-the-year is calculated using the Chao2 estimator, a bias-corrected estimator that is robust to differences in sighting probabilities among individuals (Chao 1989; Keating *et al.* 2002; Cherry *et al.* 2007). In the final step, the annual estimate of total number of females with cubs-of-the-year is combined with those of previous years to assess trend. Changes in numbers of females with cubs-of-the-year are representative of the rate of change for the entire population, but additional process variation comes from the proportion of females that have cubs-of-the-year.

Annual estimates of females with cubs-of-the-year based on Chao2 have been reported by IGBST since 2005, accompanied by the derivation of total population estimates. The model-averaged Chao2 estimates of females with cubs-of-the-year and derived total population estimates have been applied and reported by the IGBST since 2007.

As the grizzly bear population has increased, the model-averaged Chao2 population estimates have become increasingly conservative (*i.e.,* prone to underestimation), primarily due to conservative criteria of the ''rule set'' (Schwartz *et al.* 2008) as well as underestimation bias associated with the Chao2 estimator itself (Cherry *et al.* 2007). As a conservative approach to population estimation, the model-averaged Chao2 population estimator will continue to be the method used to assess criterion 1 (see YES 2016b, Appendix C, for the application protocol for deriving the annual population estimation from the model-averaged Chao2 estimate of females with cubs) until a new population estimator is approved. The IGBST may continue to investigate new methods for population estimation as appropriate; however, the model-averaged Chao2 method will continue to be used for the foreseeable future.

Schwartz *et al.* (2006b, entire) estimated survivorship of cubs-of-the-year, yearlings, and independent (2 years old or older) bears as well as reproductive performance to estimate population growth. They examined geographic patterns of population growth based on whether bears lived inside YNP, outside the Park but inside the Recovery Zone or PCA, or outside the PCA entirely. The PCA boundaries (containing 23,853 km^2 (9,210 mi^2)) correspond to those of the Yellowstone Recovery Zone (USFWS 1993, p. 41) and will replace the Recovery Zone boundary (see figure 1). Based on decreased cub and yearling survival inside YNP compared to outside YNP, Schwartz *et al.* (2006b, p. 29) concluded that grizzly bears were approaching carrying capacity inside YNP. The IGBST (2012, p. 33) documented lower cub and yearling survival than in the previous time period, results consistent with the conclusion by Schwartz *et al.* (2006b). Importantly, annual survival of independent females (the most influential age-sex cohort on population trend) remained the same while independent male survival increased (IGBST 2012, p. 33). The GYE grizzly bear population exhibited signs of density-dependent effects, suggesting that it may be approaching carrying capacity (K), including: Decreased cub survival and reproduction in areas with higher bear densities (van Manen *et al.* 2016, entire) and decreasing female home ranges (Bjornlie *et al.* 2014b, p. 4). Collectively, these studies indicate that the growth rate of the GYE grizzly bear DMA population has slowed as bear densities have approached carrying capacity, particularly in the core area of their current range.

Mortality reduction is a key part of any successful management effort for grizzly bears; however, some mortality, including most human-caused mortality, is unavoidable in a dynamic system where hundreds of bears inhabit large areas of diverse habitat with several million human visitors and residents. Adult female mortality influences the population trajectory more than mortality of males or dependent young (Eberhardt 1977, p. 210; Knight and Eberhardt 1985, p. 331; Schwartz *et al.* 2006b, p. 48). Low adult female survival was the critical factor that caused decline in the GYE population prior to the mid-1980s (Knight and Eberhardt 1985, p. 331). In the early 1980s, with the development of the first Recovery Plan (USFWS 1982, pp. 21–24), agencies began to address mortality and increased adult female survivorship (USDA FS 1986, pp. 1–2; Knight *et al.* 1999, pp. 56–57).

The most current demographic criteria were appended to the 1993 Recovery Plan in 2007, and proposed revisions to those were released for public comment in 2013, though not finalized, as explained above. Further revisions to the demographic criteria were released for public comment concurrent with the proposed rule (81 FR 13174, March 11, 2016). Below, we detail each recovery criterion that is appended to the Recovery Plan concurrent with this final rule and included in the 2016 Conservation Strategy.

To achieve mortality management in the area appropriate to the long-term conservation of the GYE population and to assure that the area of mortality management was the same as the area where the population estimates are made, the Service, based on recommendations in an IGBST report (2012), has modified the area where mortalities are counted against the total mortality limits to be the same area that is monitored for unique adult female grizzly bears with cubs-of-the-year (see *Glossary*) and in which the population size is estimated. The basis for the DMA was the boundary developed in 2007 by the Service (USFWS 2007*b*) for what was termed ''suitable habitat.'' This suitable habitat boundary (enclosing a total area of 46,035 km^2 (17,774 mi^2)) is sufficiently large to support a viable population in the long term, so that mortalities outside of it and inside the DPS could be excluded from consideration. This DMA area is thus most appropriate for applying total mortality limits. The IGBST's 2012 report noted, however, that because the suitable habitat boundary was drawn using mountainous ecoregions, there were narrow, linear areas along valley floors that did not meet the definition of suitable habitat and where population sinks may be created. These edge effects

are exacerbated in small habitat patches that are long and narrow and in wide-ranging species such as grizzly bears because they are more likely to encounter surrounding, unsuitable habitat (Woodroffe and Ginsberg 1998, p. 2126). Mortalities in these areas would be outside suitable habitat but could have disproportionate effects on the population generally contained within the suitable habitat zone, potentially acting as mortality sinks. The Service accepted the recommendation of the IGBST in the 2012 report for an alternative boundary that includes these narrow areas outside of, but largely bounded by, suitable habitat (see figure 1). The final designation of the DMA includes suitable habitat plus the potential sink areas for a total area of approximately 49,928 km^2 (19,279 mi^2) (see figure 1). The DMA contains 100 percent of the PCA and 100 percent of the suitable habitat, as shown in figure 1.

Demographic Recovery Criterion 1—Maintain a minimum population size of 500 grizzly bears [1] and at least 48 females with cubs-of-the-year in the DMA (figure 1) as indicated by methods established in published, peer-reviewed scientific literature and calculated by the IGBST using the most updated Application Protocol as posted on their Web site. If the estimate of total population size drops below 500 in any year or below 48 with cubs-of-the-year in 3 consecutive years, this criterion will not be met. The 48 females with cubs-of-the-year metric is a model-averaged number of documented unique females with cubs-of-the-year.

A minimum population size of at least 500 animals within the DMA will ensure short-term genetic health (Miller and Waits 2003, p. 4338) and is not a population goal. Population size will be quantified by methods established in published, peer-reviewed scientific literature and calculated by the IGBST using the most updated protocol, as posted on their Web site. Five hundred is a minimum population threshold and will ensure the short-term fitness of the population is not threatened by losses in genetic diversity in such an isolated population. The goal is to maintain the population well above this threshold to ensure that genetic issues are not a detriment to the short-term genetic fitness of the GYE grizzly bear population. The Service will initiate a formal status review if the total population estimate is less than 500 inside the DMA in any year or if counts of females with cubs-of-the-year fall below 48 for 3 consecutive years. *Status:* This recovery criterion has been met since 2003 (see IGBST annual reports available at *https://www.usgs.gov/centers/norock/science/igbst-annual-reports?qt-science_center_objects=1#qt-sicence_center_objects*).

Demographic Recovery Criterion 2—Sixteen of 18 BMUs within the Recovery Zone (see map at *http://www.fws.gov/mountain-prairie/es/species/mammals/grizzly/Yellowstone_Recovery_Zone_map.pdf*) must be occupied by females with young, with no two adjacent bear management units unoccupied, during a 6-year sum of observations. This criterion is important as it ensures that reproductive females occupy the majority of the Recovery Zone and are not concentrated in one portion of the ecosystem. If less than 16 of 18 bear management units are occupied by females with young for 3 successive 6-year sums of observations this criterion will not be met. See table 1 below for most current 3 consecutive 6-year sums of observations data. *Status:* This recovery criterion has been met since at least 2001.

TABLE 1—DEMOGRAPHIC RECOVERY CRITERION 2 IS MEASURED BY THE NUMBER OF OCCUPIED BEAR MANAGEMENT UNITS (BMUS) FOR EACH 6-YEAR SUM OF OBSERVATIONS

	Number of BMUs occupied by females with young by year								Criteria met (16 of 18 occupied at least once)
6-year period	2008	2009	2010	2011	2012	2013	2014	2015	
2008–2013	18	18	18	16	15	18	.....	.....	Yes.
2009–2014	.....	18	18	16	15	18	18	.....	Yes.
2010–2015	.....	.....	18	16	15	18	18	17	Yes.

Demographic Recovery Criterion 3—Maintain the population within the DMA around the 2002–2014 model-averaged Chao2 population estimate average size (average = 674; 95% CI = 600–747; 90% CI = 612–735) by maintaining annual mortality limits for independent females, independent males, and dependent young as shown in table 2 in this final rule. These adjustable mortality rates were calculated as those necessary to manage the population to the modeled average Chao2 population estimate of 674 bears, which occurred during the time period that this population had a relatively flat population trajectory. If mortality limits are exceeded for any sex/age class for 3 consecutive years and any annual population estimate falls below 612 (the lower bound of the 90% confidence interval), the IGBST will produce a Biology and Monitoring Review to inform the appropriate management response. If any annual population estimate falls below 600 (the lower bound of the 95% confidence interval), this criterion will not be met and there will be no discretionary mortality (see *Glossary*), except as necessary for human safety.

The population had stabilized during the period of 2002–2014, and the mean model-averaged Chao2 population estimate over that time period was 674 (95% CI = 600–747), which is very close to the population size of 683 when the GYE population was previously delisted in 2007 (72 FR 14866, March 29, 2007). The population naturally stabilized because of reduced survival of dependent young and subadults, and lower reproduction in areas with higher grizzly bear densities, suggesting density-dependent population effects associated with the population approaching carrying capacity. The existence of lower subadult survival and occupancy by grizzly bears in almost all suitable habitat inside the DMA has been demonstrated by van Manen *et al.* (2016, entire). *Status:* This criterion has been met for all age and sex classes since 2004.

[1] This number is required to maintain short-term genetic fitness in the next few decades. It is not a population target, but a minimum.

TABLE 2—TOTAL MORTALITY RATE USED TO ESTABLISH ANNUAL TOTAL MORTALITY LIMITS FOR INDEPENDENT FEMALES, INDEPENDENT MALES, AND DEPENDENT YOUNG [1] INSIDE THE DMA.

[These mortality limits are on a sliding scale to achieve the population goal inside the DMA of the model-averaged Chao2 population size of 674 between 2002–2014 (95% CI = 600–747). For populations less than 600, there will be no discretionary mortality unless necessary for human safety.]

	Total grizzly bear population estimate *		
	≤674 %	675–747 %	>747 %
Total mortality rate for independent FEMALES	<7.6	9	10
Total mortality rate for independent MALES.	15	20	22
Total mortality rate for DEPENDENT YOUNG	<7.6	9	10

Total mortality: Documented known and probable grizzly bear mortalities from all causes including but not limited to: management removals, illegal kills, mistaken identity kills, self-defense kills, vehicle kills, natural mortalities, undetermined-cause mortalities, grizzly bear hunting, and a statistical estimate of the number of unknown/unreported mortalities.

* Using the model-averaged Chao2 estimate.

[1] Total mortality rates are based on the mortality percentage of the respective population segment relative to the population estimates.

The 2016 Conservation Strategy

In order to document the regulatory mechanisms and coordinated management approach necessary to ensure the long-term maintenance of a recovered population, the Recovery Plan calls for the development of ''a conservation strategy to outline habitat and population monitoring that will continue in force after recovery'' (Recovery Plan Task Y426) (USFWS 1993, p. 55). To accomplish this goal, a Conservation Strategy Team was formed in 1993. This team included biologists and managers from the Service, NPS, USFS, USGS, IDFG, WGFD, and MFWP.

In March 2000, a draft Conservation Strategy for the GYE was released for public review and comment (65 FR 11340, March 2, 2000). Also in 2000, a Governors' Roundtable was organized to provide recommendations from the perspectives of the three States that would be involved with grizzly bear management after delisting. In 2003, the draft Final Conservation Strategy for the Grizzly Bear in the GYE was released, along with drafts of State grizzly bear management plans (all accessible at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php*). We responded to all public comments and peer reviews received on the Conservation Strategy and involved partners finalized the Conservation Strategy, which was published in the **Federal Register** in 2007 (72 FR 11376, March 13, 2007).

Revisions were made to the Conservation Strategy, and a draft 2016 Conservation Strategy was presented for public comment concurrent with the proposed rule to delist the GYE grizzly bear DPS (81 FR 13174, March 11, 2016). The 2016 Conservation Strategy was finalized on December 16, 2016 (available at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php*). Both the 2007 and 2016 Conservation Strategies describe the coordinated, multi-agency efforts to monitor and manage the GYE grizzly bear population that have been ongoing for decades. These efforts contributed to the recovery of the GYE grizzly bear and will ensure the maintenance of a recovered population. The most significant change between the 2007 and 2016 Conservation Strategies is the update of the demographic recovery criteria to reflect revisions to the Recovery Plan based on the best available science.

The 2016 Conservation Strategy will guide post-delisting management of the GYE grizzly bear population for the foreseeable future, beyond the minimum 5-year post-delisting monitoring period required by the Act. The purposes of the 2016 Conservation Strategy and associated State, Tribal, and Federal implementation plans are to: (1) Describe, summarize, and implement the coordinated efforts to manage the grizzly bear population and its habitat to ensure continued conservation of the GYE grizzly bear population; (2) specify and implement the population/mortality management, habitat, and conflict bear standards to maintain a recovered grizzly bear population for the future; (3) document specific State, Tribal, and Federal regulatory mechanisms and legal authorities, policies, management, and monitoring programs that exist to maintain the recovered grizzly bear population; and (4) document the actions that participating agencies have agreed to implement (YES 2016a, pp. 1–12).

Implementation of the 2016 Conservation Strategy by all agency partners will coordinate management and monitoring of the GYE grizzly bear population and its habitat after delisting. The 2016 Conservation Strategy summarizes the regulatory framework that Federal and State agencies will use for management of the GYE grizzly bear population after delisting. The 2016 Conservation Strategy also identifies and defines adequate post-delisting monitoring to maintain a healthy GYE grizzly bear population (YES 2016a, pp. 33–85). The 2016 Conservation Strategy has objective, measurable habitat and population standards, with clear State and Federal management responses if deviations occur (YES 2016a, pp. 100–103). It represents 20 years of a collaborative, interagency effort among the members of the YES. State grizzly bear management plans were developed in all three affected States (Idaho, Montana, and Wyoming) and are incorporated into the final 2016 Conservation Strategy as appendices (accessible at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php*). All State and Federal agencies party to the 2016 Conservation Strategy signed a memorandum of understanding (MOU) agreeing to implement the 2016 Conservation Strategy prior to publication of this final rule.

The 2016 Conservation Strategy identifies and provides a framework for managing habitat within the PCA and managing demographic parameters within the DMA (see figure 1). The PCA contains adequate seasonal habitat components for a portion of the recovered GYE grizzly bear population for the future and to allow bears to continue to expand outside the PCA. The PCA includes approximately 51 percent of suitable grizzly bear habitat within the GYE, and approximately 75 percent of the population of female grizzly bears with cubs-of-the-year spent part or all of the year within the PCA (Haroldson 2014a, *in litt.*) (For more information about what constitutes ''suitable habitat,'' see the *Suitable*

Habitat discussion under *Factor A,* below).

The 2016 Conservation Strategy will be implemented and funded by Federal, Tribal, and State agencies within the GYE. The signatories to the final 2016 Conservation Strategy have a demonstrated track record of funding measures to ensure recovery of this grizzly bear population for more than 3 decades. Post delisting, mortality management will be the responsibility of State fish and wildlife agencies. In general, the USFS and NPS will be responsible for habitat management to reduce the risk of human-caused mortality to grizzly bears, while the NPS, and State and Tribal wildlife agencies, will be responsible for managing the population within specific total mortality limits within their respective areas of responsibility. The USFS and NPS collectively manage approximately 98 percent of lands inside the PCA. Specifically, YNP; GTNP; and the Shoshone, Beaverhead-Deerlodge, Bridger-Teton, Caribou-Targhee, and Custer Gallatin National Forests are the Federal entities responsible for implementing the 2016 Conservation Strategy. Affected National Forests and National Parks have incorporated the habitat standards and criteria into their Forest Plans and National Park management plans and/or Superintendent's Compendia via appropriate amendment processes so that they are legally applied to these public lands within the GYE (USDA FS 2006b, p. 4; YNP 2014b, p. 18; GTNP and JDR 2016, p. 3). Outside of the PCA, grizzly bear habitat is well protected via Wilderness Area designation (Wilderness or Wilderness Study Area (WSA)) or Forest Plan direction, and demographic standards will protect the population throughout the DMA.

When this final rule goes into effect, the YGCC will replace the YES as the interagency group coordinating implementation of the 2016 Conservation Strategy's habitat and population standards, and monitoring (YES 2016a, pp. 96–98). Similar to the YES, the YGCC members include representatives from YNP, GTNP, the five affected National Forests, BLM, USGS, IDFG, MFWP, WGFD, one member from local county governments within each State, and one member from the Shoshone Bannock, Northern Arapahoe, and Eastern Shoshone Tribes. Through this action, the Service is transferring primary management authority from the Service to the States, other Federal agencies, and the Tribes; therefore, the Service is not a member of the YGCC. The Service Grizzly Bear Recovery Coordinator and the IGBST Team Leader will serve as advisors to the YGCC as they did to the YES. All meetings will be open to the public. Besides coordinating management, research, and financial needs for successful conservation of the GYE grizzly bear population, the YGCC will review the IGBST Annual Reports and review and respond to any deviations from habitat or population standards. As per the implementation section of the 2016 Conservation Strategy, the YGCC will coordinate management and implementation of the 2016 Conservation Strategy and work together to rectify problems and to ensure that the habitat and population standards and total mortality limits will be met and maintained.

The 2016 Conservation Strategy is an adaptive, dynamic document that establishes a framework to incorporate new and better scientific information as it becomes available or as necessary in response to environmental changes. The signatories to the 2016 Conservation Strategy have agreed that any changes and updates to the 2016 Conservation Strategy will occur only if they are based on the best available science, and subject to public comment before being implemented by the YGCC (YES 2016a, pp. 2, 18).

Distinct Vertebrate Population Segment Policy Overview

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. ''Species'' is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). We, along with the National Marine Fisheries Service (NMFS) (now the National Oceanic and Atmospheric Administration—Fisheries), developed the Policy Regarding the Recognition of Distinct Vertebrate Population Segments (DPS policy) (61 FR 4722, February 7, 1996), to help us in determining what constitutes a distinct population segment (DPS). Under this policy, the Service considers two factors to determine whether the population segment is a valid DPS: (1) Discreteness of the population segment in relation to the remainder of the taxon to which it belongs; and (2) the significance of the population segment to the taxon to which it belongs. If a population meets both tests, it is a DPS, and the Service then evaluates the population segment's conservation status according to the standards in section 4 of the Act for listing, delisting, or reclassification (*i.e.,* is the DPS endangered or threatened). Our policy further recognizes it may be appropriate to assign different classifications (*i.e.,* endangered or threatened) to different DPSs of the same vertebrate taxon (61 FR 4725, February 7, 1996).

Past Practice and History of Using DPSs

As of April 11, 2017, of the 439 native vertebrate listings, 97 are listed as less than an entire taxonomic species or subspecies (henceforth referred to in this discussion as populations) under one of several authorities, including the ''distinct population segment'' language in the Act's definition of species (section 3(16)). Twenty-three of these 97 populations, which span 5 different taxa, predate either the 1978 amendments to the ESA which revised the definition of ''species'' to include DPSs of vertebrate fish and wildlife or the 1996 DPS Policy; as such, the final listing determinations for these populations did not include formal policy-based analyses or expressly designate the listed entity as a DPS. In several instances, however, the Service and NMFS have established a DPS and revised the List of Endangered and Threatened Wildlife in a single action, as shown in several of the following examples (see proposed rule for further details, 81 FR 13174, March 11, 2016) for the brown pelican (*Pelecanus occidentalis*) (50 FR 4938, February 4, 1985; 74 FR 59444, November 17, 2009), gray whale (*Eschrichtius robustus*) (59 FR 31094, June 16, 1994), Steller sea lion (*Eumetopias jubatus*) (62 FR 24345, May 5, 1997), Columbian white-tailed deer (*Odocoileus virginianus leucurus*) (68 FR 43647, July 24, 2003; 80 FR 60850, October 8, 2015), American crocodile (*Crocodylus acutus*) (72 FR 13027, March 20, 2007), loggerhead sea turtle (*Caretta caretta*) (76 FR 58868, September 22, 2011), green sea turtle (*Chelonia mydas*) (81 FR 20058, April 6, 2016), and humpback whale (*Megaptera novaeangliae*) (81 FR 93639, December 21, 2016). Although some of these examples predate the DPS policy, the authority to list and delist DPSs had already been clearly established with the 1978 amendments to the ESA.

Our authority to make these determinations and to revise the list accordingly is a reasonable interpretation of the language of the Act, and our ability to do so is an important component of the Service's program for the conservation of endangered and threatened species. Our authority to revise the existing listing of a species (the grizzly bear in the lower 48 States) to identify a GYE DPS and determine

that it is healthy enough that it no longer needs the Act's protections is found in the precise language of the Act. Moreover, even if that authority were not clear, our interpretation of this authority to make determinations under section 4(a)(1) of the Act and to revise the endangered and threatened species list to reflect those determinations under section 4(c)(1) of the Act is reasonable and fully consistent with the Act's text, structure, legislative history, relevant judicial interpretations, and policy objectives.

On December 12, 2008, a formal opinion was issued by the Solicitor, ''U.S. Fish and Wildlife Service Authority Under Section 4(c)(1) of the Endangered Species Act to Revise Lists of Endangered and Threatened Species to 'Reflect Recent Determinations''' (M–37018, U.S. DOI 2008). The Service fully agrees with the analysis and conclusions set out in the Solicitor's Memorandum opinion. This final action is consistent with the opinion. The complete text of the Solicitor's opinion can be found at *https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M–37018.pdf.*

We recognize that our interpretation and use of the DPS policy to revise and delist distinct population segments has been challenged in *Humane Society of the United States* v. *Jewell,* 76 F.Supp.3d 69 (D. DC 2014). Partly at issue in that case was our application of the DPS policy to Western Great Lakes wolves in a delisting rule (76 FR 81666, December 28, 2011). Our rule was vacated by the district court's decision. We respectfully disagree with the district court's interpretation of the DPS policy, and the United States has appealed that decision. *Humane Society of the United States* v. *Jewell,* case no. 15–5041 (D.C. Cir.). No decision has been issued on that litigation.

In the 1993 Grizzly Bear Recovery Plan, the Service identifies six grizzly bear ecosystems and identifies unique demographic recovery criteria for each one (see map at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php*). The 1993 Recovery Plan states that ''grizzly bear populations may be listed, recovered, and delisted separately'' and that it is the intent of the Service to delist individual populations as they achieve recovery (USFWS 1993, pp. ii, 16–17). The Service has proceeded in a manner consistent with the Recovery Plan with respect to individual population treatment. For example, grizzly bears in the Cabinet-Yaak, Selkirk, and North Cascades Ecosystems, all included in the original grizzly bear listing, were petitioned for reclassification from threatened to endangered. Although already listed as threatened, we determined that reclassifying those grizzly bears to endangered was warranted but precluded by higher priorities beginning in 1991 for the North Cascades (56 FR 33892, July 24, 1991), 1993 for the Cabinet-Yaak (58 FR 8250, February 12, 1993), and 1999 for the Selkirk Ecosystems (64 FR 26725, May 17, 1999). In 2014, the Service determined that the Cabinet-Yaak and Selkirk Ecosystems had recovered to the point that they were no longer warranted but precluded from listing as endangered; they remain listed as threatened (79 FR 72487, December 5, 2014). Grizzly bears in the North Cascades Ecosystem are still warranted but precluded for reclassification from threatened to endangered (80 FR 80606, December 24, 2015). The Bitterroot Ecosystem now has status under section 10(j) of the Act (65 FR 69624, November 17, 2000), which addresses the Service's proposal to release an experimental population of grizzly bears in that ecosystem.

Distinct Vertebrate Population Segment Analysis

Analysis of Discreteness in Relation to Remainder of Taxon

Under our DPS Policy, a population of a vertebrate taxon may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon (*i.e., Ursus arctos horribilis* in the GYE) as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation); or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) (''the inadequacy of existing regulatory mechanisms'') of the Act. The taxon (*U. a. horribilis*) is currently distributed throughout Alaska, northwestern and western Canada, and the six ecosystems in the lower 48 States (Schwartz *et al.* 2003, pp. 557–558). The DPS Policy does not require complete separation of one DPS from another, and occasional interchange does not undermine the discreteness of potential DPSs. If complete separation is required, the loss of the population has little significance to other populations (61 FR 4722, 4724, February 7, 1996). The DPS policy requires only that populations be ''markedly separated'' from each other. Thus, if occasional individual grizzly bears move between populations, the population could still display the required level of discreteness per the DPS Policy. The standard adopted allows for some limited interchange among population segments considered to be discrete, so that loss of an interstitial population could well have consequences for gene flow and demographic suitability of a species as a whole.

Although the DPS Policy does not allow State or other intra-national governmental boundaries to be used as the basis for determining the discreteness of a potential DPS, an artificial or human-made boundary may be used to clearly identify the geographic area included within a DPS designation. Easily identified human-made objects, such as the center line of interstate highways, Federal highways, and State highways are useful for delimiting DPS boundaries. Thus, the GYE grizzly bear DPS consists of: that portion of Idaho that is east of Interstate Highway 15 and north of U.S. Highway 30; that portion of Montana that is east of Interstate Highway 15 and south of Interstate Highway 90; and that portion of Wyoming that is south of Interstate Highway 90, west of Interstate Highway 25, west of Wyoming State Highway 220, and west of U.S. Highway 287 south of Three Forks (at the 220 and 287 intersection, and north of Interstate Highway 80 and U.S. Highway 30) (see DPS boundary in figure 1). Due to the use of highways as easily described boundaries, large areas of unsuitable habitat are included in the DPS boundaries.

The core of the GYE grizzly bear DPS is the Yellowstone PCA (24,000 km^2 (9,200 mi^2)) (USFWS 1993, p. 39). The Yellowstone PCA includes YNP; a portion of GTNP; JDR; sizable contiguous portions of the Shoshone, Bridger-Teton, Caribou-Targhee, Custer Gallatin, and Beaverhead-Deerlodge National Forests; BLM lands; and surrounding State and private lands (USFWS 1993, p. 39). As grizzly bear populations have rebounded and densities have increased, bears have expanded their current range beyond the PCA, into other suitable habitat in the DMA. Grizzly bears now occupy about 44,624 km^2 (17,229 mi^2) or 89 percent of the GYE DMA (Haroldson 2015, *in litt.*), with occasional occurrences well beyond this estimate of current range. No grizzly bears originating from the GYE have been suspected or confirmed beyond the borders of the GYE grizzly bear DPS described above. Similarly, no grizzly bears originating from other ecosystems have been detected inside the borders of

the GYE grizzly bear DPS (Wildlife Genetics International 2014, *in litt.*).

The GYE grizzly bear population is the southernmost population remaining in the conterminous United States and has been physically separated from other areas where grizzly bears occur for at least 100 years (Merriam 1922, pp. 1–2; Miller and Waits 2003, p. 4334). The nearest population of grizzly bears is found in the NCDE approximately 115 km (70 mi) to the north. Although their current range continues to expand north (Bjornlie *et al.* 2014a, p. 185), grizzly bears from the GYE have not been documented north of Interstate 90 outside the DPS boundaries (Frey 2014, *in litt.*). Over the last few decades, the NCDE grizzly bear population has been slowly expanding to the south, and there have been several confirmed grizzly bears from the NCDE within 32 to 80 km (20 to 50 mi) of the GYE grizzly bear DPS boundaries near Butte, Deerlodge, and Anaconda, Montana (Jonkel 2014, *in litt.*). However, there is currently no known connectivity between these two grizzly bear populations.

Genetic data also support the conclusion that grizzly bears from the GYE are separated from other grizzly bears. Genetic studies estimating heterozygosity (which provides a measure of genetic diversity) show 60 percent heterozygosity in the GYE grizzly bears compared to 67 percent in the NCDE grizzly bears (Haroldson *et al.* 2010, p. 7). Heterozygosity is a useful measure of genetic diversity, with higher values indicative of greater genetic variation and evolutionary potential. High levels of genetic variation are indicative of high levels of connectivity among populations or high numbers of breeding animals. By comparing heterozygosity of extant bears to samples from Yellowstone grizzly bears of the early 1900s, Miller and Waits (2003, p. 4338) concluded that gene flow and, therefore, population connectivity between the GYE grizzly bear population and populations to the north was low even 100 years ago. The reasons for this historic limitation of gene flow are unclear, but we do know increasing levels of human activity and settlement in this intervening area over the last century further limited grizzly bear movements into and out of the GYE, likely resulting in the current lack of connectivity (Proctor *et al.* 2012, p. 35).

Based on the best available scientific data about grizzly bear locations and movements, we find that the GYE grizzly bear population and other remaining grizzly bear populations are markedly, physically separated from each other. Therefore, the GYE grizzly bear population meets the criterion of discreteness under our DPS Policy. Occasional movement of bears from other grizzly bear populations into the GYE grizzly bear population would be beneficial to its long-term persistence (Boyce *et al.* 2001, pp. 25, 26). While future connectivity is desirable and will be actively managed for, this would not undermine discreteness, as all that is required is ''marked separation,'' not absolute separation. Even if occasional individual grizzly bears disperse among populations, the GYE grizzly bear population would still display the required level of discreteness per the DPS Policy. And, as stated in the 1993 Recovery Plan, we recognize that natural connectivity is important to long-term grizzly bear conservation, and we will continue efforts to work toward this goal independent of the delisting of the GYE grizzly bear DPS (USFWS 1993, p. 53). This issue is discussed further under *Factor E* below.

Analysis of Significance of Population Segment to Taxon

If we determine that a population segment is discrete under one or more of the conditions described in the Service's DPS policy, its biological and ecological significance will then be considered in light of Congressional guidance that the authority to list DPS's be used ''sparingly'' while encouraging the conservation of genetic diversity (see Senate Report 151, 96th Congress, 1st Session). In carrying out this examination, we consider available scientific evidence of the population's importance to the taxon (*i.e., Ursus arctos horribilis*) to which it belongs. As noted previously, grizzly bears once lived throughout the North American Rockies from Alaska and Canada, and south into central Mexico. Grizzly bears have been extirpated from most of the southern portions of their historic range and the Canadian plains (Schwartz *et al.* 2003, pp. 557–558). Since precise circumstances are likely to vary considerably from case to case, the DPS policy does not describe all the classes of information that might be used in determining the biological and ecological importance of a discrete population. However, the DPS policy describes four possible classes of information that provide evidence of a population segment's biological and ecological importance to the taxon to which it belongs.

As specified in the DPS policy (61 FR 4722, February 7, 1996), this consideration of the population segment's significance may include, but is not limited to, the following: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; or (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics. To be considered significant, a population segment needs to satisfy only one of these conditions, or other classes of information that might bear on the biological and ecological importance of a discrete population segment, as described in the DPS policy (61 FR 4722, February 7, 1996). Below we address Factors 1, 2, and 4. Factor 3 does not apply to the GYE grizzly bear population because there are several other naturally occurring populations of grizzly bears in North America.

Unusual or Unique Ecological Setting

In the 2007 final rule, we concluded that the GYE was a unique ecological setting because GYE grizzly bears were more carnivorous than in other ecosystems where the taxon occurs and they still used whitebark pine seeds extensively while other populations no longer did. New research shows that meat constitutes approximately the same percentage of annual grizzly bear diets in the NCDE (38 and 56 percent for females and males, respectively) (Teisberg *et al.* 2014b, p. 7) and the GYE (44 percent of all GYE grizzly bears) (Schwartz *et al.* 2014a, p. 75). We also now have information suggesting that whitebark pine has been reduced in the GYE since 2002 and, therefore, may not be as major of a food source as previously concluded (see 72 FR 14866, March 29, 2007). Although consumption of meat and whitebark pine by GYE grizzly bears individually may not be exceptional, we believe that the combination of food sources in the GYE grizzly bear, including army cutworm moths, whitebark pine, cutthroat trout, and ungulates (bison, elk, moose (*Alces alces*), and deer (*Odocoileus* species)) (Schwartz *et al.* 2003, p. 568) comprises a unique ecological setting because we are unaware of any other population of *Ursus arctos horribilis* that utilizes this combination.

In addition to the unique combination of food sources available in the GYE, there is a gradient of foraging strategies across the ecosystem with bears in different parts of the GYE having access

to different combinations of these food sources (see figure 2 in Gunther *et al.* 2014, p. 68). Mealey (1980, entire) documented three ''feeding economies'' within YNP alone. Grizzly bears in the core (*i.e.,* around Yellowstone Lake) of the GYE consume ungulates (primarily elk and bison, winter killed or usurped from wolf kills), cutthroat trout, whitebark pine, and army cutworm moths as a regular part of their diets (Fortin *et al.* 2013a, pp. 271, 275–276; see figure 2 in Gunther *et al.* 2014, p. 68). We are not aware of other populations that contain this combination of food sources. As the population extends out from the core, bears have access to some but not all of the main foods in the core. While elk are available to grizzly bears throughout most of the GYE, army cutworm moths are only available on the east side and whitebark pine is only available to two-thirds of grizzly bears (Costello *et al.* 2014, p. 2009; see figure 2 in Gunther *et al.* 2014, p. 68).

Although grizzly bears in other ecosystems consume meat in similar quantities as the GYE, grizzly bears in the GYE are unique in their consumption of bison (Mattson 1997, p. 167; Fortin *et al.* 2013a, p. 275; Gunther 2017, *in litt.*) and in their interactions with wolves to obtain carcasses (Ballard *et al.* 2003, pp. 261–262; Smith *et al.* 2003, p. 336; Metz *et al.* 2012, p. 556). In addition, GYE grizzly bears have been documented to consume unique food items such as geothermal soil (Mattson *et al.* 1999, p. 109) and false-truffles (Fortin *et al.* 2013a, p. 277; Gunther *et al.* 2014, p. 64). We are not aware of other grizzly bear populations that consume these food items. GYE grizzly bears opportunistically feed on more than 260 species of food to supplement their diets (Gunther *et al.* 2014, entire), which is more than other populations of grizzly bears of which we are aware. This unique combination of food sources utilized by grizzly bears in the GYE is significant because of the potential conservation value provided by variation in food availability and use by grizzly bears in light of potential environmental changes (Lesica and Allendorf 1995, p. 756; Bunnell *et al.* 2004, p. 2242).

In light of these new data indicating that grizzly bears in the GYE consume a unique combination of food sources compared to other grizzly bear populations, where we have considerable information about the taxon's diet, we consider the GYE grizzly bear population to meet the DPS policy standard for significance based on its persistence in an ecological setting unusual or unique for the taxon.

Significant Gap in the Range of the Taxon

Historically, grizzly bears were distributed throughout the North American Rockies from Alaska and Canada, and south into central Mexico. Grizzly bears have been extirpated from most of the southern portions of their historic range and the Canadian plains (Schwartz *et al.* 2003, pp. 557–558). Given the grizzly bear's historic occupancy of the conterminous United States and the portion of the taxon's historic range the conterminous United States represent, recovery in the lower 48 States where the grizzly bear existed in 1975 when it was listed has long been viewed as important to the taxon (40 FR 31734, July 28, 1975). The GYE grizzly bear population is significant in achieving the Recovery Plan objectives, as it is one of only five known occupied areas and one unoccupied area and constitutes approximately half of the estimated number of grizzly bears remaining in the conterminous 48 States. Today, the GYE grizzly bear population represents the southernmost reach of the taxon. The loss of this population would significantly impact representation of the species because it would substantially curtail the range of the grizzly bear in North America by moving the range approximately 3 degrees of latitude or 200 mi (350 km) to the north. The extirpation of peripheral populations, such as the GYE grizzly bear population, is concerning because of the potential conservation value that peripheral populations can provide to the subspecies (Lesica and Allendorf 1995, p. 756; Fraser 2000, p. 50; Bunnell *et al.* 2004, p. 2242). Specifically, peripheral populations can possess slight genetic or phenotypic divergence from the core populations, which may be central to the survival of the subspecies in the face of environmental changes (Lesica and Allendorf 1995, p. 756; Bunnell *et al.* 2004, p. 2242). Therefore, we find that the GYE population of grizzly bears meets the significance criterion under our DPS policy because its loss would represent a significant gap in the range of the taxon.

Marked Genetic Differences

Several studies have documented some level of genetic differences between grizzly bears in the GYE and other populations in North America (Paetkau *et al.* 1998, pp. 421–424; Waits *et al.* 1998, p. 310; Proctor *et al.* 2012, p. 12). The GYE population has been isolated from other grizzly bear populations for 100 years or more (Miller and Waits 2003, p. 4334). However, Miller and Waits (2003, p. 4334) could only speculate as to the reasons behind this historical separation or how long it had been occurring. Proctor *et al.* (2012, p. 35) concluded that observed differences in heterozygosity among grizzly bear populations in southern Canada and the United States were an artifact of human-caused habitat fragmentation, not the result of different evolutionary pressures selecting for specific traits. We do not know whether these differences in heterozygosity levels are biologically meaningful, and we have no data indicating they are. Because we do not know the biological significance (if any) of the observed differences, we cannot say with certainty that the GYE grizzly bear population's genetics differ ''markedly'' from other grizzly bear populations. Therefore, we do not consider these genetic differences to meet the DPS policy's standard for significance.

In summary, while we no longer consider the GYE grizzly bear population to be significant due to marked genetic differences, we still conclude that the GYE grizzly bear population is significant due to its persistence in an ecological setting unique for the taxon and because the loss of this population would result in a significant gap in the range of the taxon.

Summary of Distinct Population Segment Analysis

Based on the best scientific and commercial data available, as described above, we find that the GYE grizzly bear population is discrete from other grizzly bear populations and significant to the remainder of the taxon (*i.e., Ursus arctos horribilis*). Because the GYE grizzly bear population is discrete and significant, it meets the definition of a DPS under the Act. Therefore, the GYE grizzly bear DPS is a listable entity under the Act, and we now assess this DPS's conservation status in relation to the Act's standards for listing, delisting, or reclassification (*i.e.,* whether this DPS meets the definition of an endangered or threatened species under the Act).

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. ''Species'' is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment

of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We must consider these same five factors in delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered nor threatened for the following reasons: (1) The species is extinct; (2) the species has recovered and is no longer endangered or threatened; and/or (3) the original scientific data used at the time the species was classified were in error.

A recovered species is one that no longer meets the Act's definition of endangered or threatened. A species is endangered for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range (SPR) and is threatened if it is likely to become endangered in the foreseeable future throughout all or a significant portion of its range. The word ''range'' in ''significant portion of its range'' refers to the range in which the species currently exists at the time of this status review. Determining whether a species is recovered requires consideration of the same five categories of threats specified in section 4(a)(1) of the Act. For species that are already listed as endangered or threatened, this analysis of threats is an evaluation of both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following the removal of the Act's protections. For the purposes of this analysis, we first evaluate the status of the species throughout all of its range, then consider whether the species is in danger of extinction or likely to become so in any significant portion of its range.

In considering what factors might constitute threats, we must look beyond the exposure of the species to a particular factor to evaluate whether the species may respond to the factor in a way that causes actual impacts to the species. If there is exposure to a factor and the species responds negatively, the factor may be a threat, and during the five-factor threats analysis, we attempt to determine how significant a threat it is. The threat is significant if it drives or contributes to the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined by the Act. However, the identification of factors that could affect a species negatively may not be sufficient to justify a finding that the species warrants listing. The information must include evidence sufficient to suggest that the potential threat is likely to materialize and that it has the capacity (*i.e.,* it should be of sufficient magnitude and extent) to affect the species' status such that it meets the definition of endangered or threatened under the Act. The following analysis examines the five factors affecting, or likely to affect, the GYE grizzly bear population within the foreseeable future. We previously concluded that GYE grizzly bears are recovered and warranted delisting (72 FR 14866, March 29, 2007). In this final rule, we make a determination as to whether the distinct population segment of GYE grizzly bears is an endangered or threatened species, based on the best scientific and commercial information available. In so doing, we address the issues raised by the Ninth Circuit in *Greater Yellowstone Coalition* v. *Servheen,* 665 F.3d 1015 (9th Cir. 2011), which were briefly discussed above.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Factor A requires the Service to consider present or threatened destruction, modification, or curtailment of grizzly bear habitat or its range. Here, the following considerations warrant discussion regarding the GYE grizzly bear population, effects due to: (1) Motorized access management, (2) developed sites, (3) livestock allotments, (4) mineral and energy development, (5) recreation, (6) snowmobiling, (7) vegetation management, (8) climate change, and (9) habitat fragmentation.

Habitat destruction and modification were contributing factors leading to the listing of the grizzly bear as a threatened species under the Act in 1975 (40 FR 31734, July 28, 1975). Both the dramatic decreases in historical range and land management practices in formerly secure grizzly bear habitat led to the 1975 listing (40 FR 31734, July 28, 1975). For consideration under the Act's listing provisions in this final rule, the word range applies to where the species currently exists. To address this source of population decline, the IGBST was created in 1973, to collect, manage, analyze, and distribute science-based information regarding habitat and demographic parameters upon which to base management and recovery. Then, in 1983, the IGBC was created to coordinate management efforts across multiple Federal lands and different States within the various ecosystems ultimately working to achieve recovery of the grizzly bear in the lower 48 States. Its objective was to change land management practices on Federal lands that supported grizzly bear populations at the time of listing to provide security and maintain or improve habitat conditions for the grizzly bear. Since 1986, National Forest and National Park plans have incorporated the Interagency Grizzly Bear Guidelines (USDA FS 1986, pp. 1–2) to manage grizzly bear habitat in the Yellowstone PCA.

Management improvements made as a result of the Interagency Grizzly Bear Guidelines include, but are not limited to: (1) Federal and State agency coordination to produce nuisance bear guidelines that allow a quick response to resolve and minimize grizzly bear-human confrontations; (2) reduced motorized access route densities through restrictions, decommissioning, and closures; (3) highway design considerations to facilitate population connectivity; (4) seasonal closure of some areas to all human access in National Parks that are particularly important to grizzly bears; (5) closure of many areas in the GYE to oil and gas leasing, or implementing restrictions such as no surface occupancy; (6) elimination of six active and four vacant sheep allotments on the Caribou-Targhee National Forest since 1998, resulting in an 86 percent decrease in total sheep animal months inside the Yellowstone PCA; and (7) expanded information and education (I&E) programs in the Yellowstone PCA to help reduce the number of grizzly bear mortalities caused by big-game hunters (outside National Parks). Overall, adherence to the Interagency Grizzly Bear Guidelines has changed land management practices on Federal lands to provide security and to maintain or improve habitat conditions for the grizzly bear. Implementation of these guidelines has led to the successful rebound of the GYE grizzly bear population, allowing it to significantly increase in size and distribution since its listing in 1975.

In December 2016, the YES released the final 2016 Conservation Strategy for the grizzly bear in the GYE to guide management and monitoring of the habitat and population of GYE grizzly bears after delisting. The 2016 Conservation Strategy is the most recent iteration of the Conservation Strategy, which was first published in final form in 2007 (see our notice of availability published on March 13, 2007, at 72 FR

11376). The 2016 Conservation Strategy incorporates the explicit and measurable habitat criteria established in the ''Recovery Plan Supplement: Habitat-based Recovery Criteria for the Greater Yellowstone Ecosystem'' (USFWS 2007*b*). Whereas the Interagency Grizzly Bear Guidelines helped to guide successful recovery efforts, the 2016 Conservation Strategy will help guide the recovered GYE population post-delisting. The 2016 Conservation Strategy identifies and provides a framework for managing two areas, the PCA and adjacent areas of the DMA, where occupancy by grizzly bears is anticipated to continue in the foreseeable future. What follows is an assessment of present or threatened destruction, modification, or curtailment of the grizzly bear's habitat within the PCA and adjacent areas of the DMA.

Habitat Management Inside the Primary Conservation Area

As per the 2016 Conservation Strategy and the habitat-based recovery criteria discussed above, the PCA will be a core secure area for grizzly bears where human impacts on habitat conditions will be maintained at or below levels that existed in 1998 (YES 2016a, pp. 54–73). Specifically, the amount of secure habitat will not decrease below 1998 levels while the number and capacity of developed sites and the number and acreage of livestock allotments will not increase above 1998 levels. The majority of land, all suitable habitat, within the PCA is managed by the NPS (39.4 percent (9,409 of 23,853 km^2 (3,632 of 9,210 mi^2)) and the USFS (58.5 percent (13,942 of 23,853 km^2 (5,383 of 9,210 mi^2)). The 1998 baseline standards have been incorporated into the National Park Compendia (YNP 2014b, p. 18; GTNP and JDR 2016, p. 3) and the USFS Amendment for Grizzly Bear Habitat Conservation for the Greater Yellowstone Area National Forests (USDA FS 2006b, entire). The 1998 baseline for habitat standards was chosen because the levels of secure habitat and developed sites on public lands remained relatively constant in the 10 years preceding 1998 (USDA FS 2004, pp. 140–141), and the selection of 1998 ensured that habitat conditions existing at a time when the population was increasing at a rate of 4 to 7 percent per year (Schwartz *et al.* 2006b, p. 48) would be maintained. For each of the 40 bear management subunits, located in the PCA, the 1998 baseline was determined through a GIS analysis of the amount of secure habitat, open and closed road densities, the number and capacity of livestock allotments, and the number and capacity of developed sites on public lands.

Motorized Access Management: When we listed the grizzly bear in 1975, we identified land management practices that create new ways for humans to access formerly secure grizzly bear habitat as the mechanism that resulted in bears being more susceptible to the threat of human-caused mortality and human-bear conflicts (40 FR 31734, July 28, 1975). We recognized early on that managing this human access to grizzly bear habitat would be the key to effective habitat management, and an extensive body of literature supports this approach. Specifically, unmanaged motorized access impacts grizzly bears by: (1) Increasing human interaction and potential grizzly bear mortality risk; (2) increasing displacement from important habitat; (3) increasing habituation to humans; and (4) decreasing habitat where energetic requirements can be met with limited disturbance from humans (Mattson *et al.* 1987, pp. 269–271; McLellan and Shackleton 1988, pp. 458–459; McLellan 1989, pp. 1862–1864; Mace *et al.* 1996, pp. 1402–1403; Schwartz *et al.* 2010, p. 661).

Motorized access affects grizzly bears primarily through increased human-caused mortality risk (Schwartz *et al.* 2010, p. 661). Secondarily, motorized access may affect grizzly bears through temporary or permanent habitat loss due to human disturbance. Managing motorized access by providing large proportions of secure habitat helps ameliorate the impacts of displacement and increased human-caused mortality risk in grizzly bear habitat. Secure habitat refers to those areas with no motorized access that are at least 4 ha (10 ac) in size and more than 500 m (1,650 ft) from a motorized access route or recurring helicopter flight line (USDA FS 2004, p. 18). In the 1998 baseline, secure habitat comprised 45.4 to 100 percent of the total area within a given subunit with an average of 85.6 percent throughout the entire PCA (YES 2016b, Appendix E). These levels of secure habitat have been successfully maintained and will continue to be maintained or improved, as directed by the 2016 Conservation Strategy and the MOU signed by all State and Federal partner agencies (YES 2016a, pp. 13–14). Thirty-seven subunits were determined to have sufficient levels of secure habitat. Three subunits were identified as in need of improvement from 1998 levels. These subunits have shown on average a 7.5 percent increase in secure habitat, and these improved levels will serve as the new baseline for these three subunits with the implementation of the 2006 Gallatin National Forest Travel Management Plan (Gallatin NF 2006, pp. 30, 83–84). Because of the positive effect that secure habitat has on grizzly bear survival and reproduction, one of the 2016 Conservation Strategy objectives is no net decrease in the 1998 baseline levels of secure habitat inside the PCA so that the PCA can continue to function as a source area for grizzly bears in the GYE. Therefore, motorized access management inside the PCA does not currently pose a threat to the GYE grizzly bear DPS, and we do not foresee that motorized access management will pose a threat in the foreseeable future.

Developed Sites: The National Parks and National Forests within the PCA will manage developed sites at 1998 levels within each bear management subunit, with some exceptions for administrative and maintenance needs (YES 2016a, pp. 54–73). These exceptions to the 1998 baseline for administrative and maintenance needs are narrow in scope and require mitigation (*i.e.,* food storage structures) to reduce potential detrimental impacts to grizzly bears (see the 2016 Conservation Strategy for a detailed description of the exception guidance, which are referred to as application rules; YES 2016a, pp. 64–66). ''Developed sites'' refer to those sites or facilities on public land with features intended to accommodate public use or recreation. Such sites are typically identified or advertised via visitor maps or information displays as identifiable destination sites promoted by the agency. Examples of developed sites include, but are not limited to, campgrounds, picnic areas, trailheads, boat launches, rental cabins, summer homes, lodges, service stations, restaurants, visitor centers, administrative sites, and permitted resource exploration or extraction sites such as oil and gas exploratory wells, production wells, plans of operation for mining activities, and work camps.

''Administrative sites'' are those sites or facilities constructed for use primarily by government employees to facilitate the administration and management of public lands. Administrative sites are counted toward developed sites, and examples include headquarters, ranger stations, patrol cabins, park entrances, Federal employee housing, and other facilities supporting government operations. In contrast to developed or administrative sites, ''dispersed sites'' are those not associated with a developed site, such as a front-country campground. These sites are typically characterized as having no permanent agency-constructed features, are temporary in

nature, have minimal to no site modifications, have informal spacing, and possibly include primitive road access. Dispersed sites are not counted toward developed sites. Developed sites on public lands are currently inventoried and tracked in GIS databases. As of 1998, there were 593 developed sites on public land within the PCA (YES 2016b, Appendix E). As of 2014, the number of developed sites on public lands had decreased to 578 (Greater Yellowstone Area Grizzly Bear Habitat Modeling Team 2015, p. 90).

The primary concern related to developed sites is direct mortality from bear-human encounters and unsecured attractants. Secondary concerns include temporary or permanent habitat loss and displacement due to increased length of time of human use and increased human disturbance to surrounding areas. In areas of suitable habitat inside the PCA, the NPS and the USFS enforce food storage rules aimed at decreasing grizzly bear access to human foods (YES 2016a, pp. 30–31, 84–85). These regulations will continue to be enforced and are in effect for nearly all currently occupied grizzly bear habitat within the GYE grizzly bear DPS boundaries (YES 2016a, pp. 30–31, 84–85). Developed sites inside the PCA do not currently constitute a threat to the GYE grizzly bear DPS. Additionally, because the National Parks and National Forests within the PCA will continue to manage developed sites at 1998 levels within each bear management subunit, with some exceptions as per the application rules (YES 2016a, pp. 65–67), and because food storage rules will be enforced on these public lands, we do not expect developed sites inside the PCA to pose a threat to the GYE grizzly bear DPS in the foreseeable future.

Livestock Allotments: When grizzly bears were listed in 1975, the Service identified ''livestock use of surrounding national forests'' as detrimental to grizzly bears ''unless management measures favoring the species are enacted'' (40 FR 31734, July 28, 1975). Impacts to grizzly bears from livestock operations potentially include: (1) Direct mortality from control actions resulting from livestock depredation; (2) direct mortality due to control actions resulting from grizzly bear habituation and/or learned use of bear attractants, such as livestock carcasses and feed; (3) increased chances of a grizzly bear livestock conflict; (4) displacement due to livestock or related management activity; and (5) direct competition for preferred forage species.

Approximately 14 percent (45 of 311) of all human-caused grizzly bear mortalities in the GYE between 2002 and 2014 were due to management removal actions associated with livestock depredations. This human-caused mortality is the main impact to grizzly bears in the GYE associated with livestock. Increased chances of grizzly bear conflict related to livestock have been minimized through requirements to securely store and/or promptly remove attractants associated with livestock operations (*e.g.,* livestock carcasses, livestock feed, etc.). The effects of displacement and direct competition with livestock for forage are considered negligible to grizzly bear population dynamics because, even with direct grizzly bear mortality, current levels of livestock allotments have not precluded grizzly bear population growth and expansion.

The Recovery Plan Supplement: Habitat-based Recovery Criteria for the Yellowstone Ecosystem (USFWS 2007*b,* entire) and the USFS Record of Decision implementing their forest plan amendments (USDA FS 2006b, entire) established habitat standards regarding livestock allotments. The number of active livestock allotments, total acres affected, and permitted sheep animal months within the PCA will not increase above 1998 levels (USDA FS 2006b, p. 5; YES 2016a, pp. 56, 67–68). Due to the higher prevalence of grizzly bear conflicts associated with sheep grazing, existing sheep allotments will be phased out as the opportunity arises with willing permittees (USDA FS 2006b, p. 6; YES 2016a, pp. 67–68).

A total of 106 livestock allotments existed inside the PCA in 1998. Of these 1998 allotments, there were 72 active and 13 vacant cattle allotments and 11 active and 10 vacant sheep allotments, with a total of 23,090 sheep animal months (YES 2016b, Appendix E). Sheep animal months are calculated by multiplying the permitted number of animals by the permitted number of months. Any use of vacant allotments will be permitted only if the number and net acreage of allotments inside the PCA does not increase above the 1998 baseline (YES 2016a, p. 68). Since 1998, the Caribou-Targhee National Forest has closed six sheep allotments within the PCA, while the Shoshone National Forest has closed two sheep allotments and the Gallatin National Forest has closed four (Greater Yellowstone Area Grizzly Bear Habitat Modeling Team 2015, p. 86). This situation has resulted in a reduction of 21,120 sheep animal months, a 91 percent reduction, from the total calculated for 1998 within the PCA, and is a testament to the commitment that land management agencies have to the ongoing success of the grizzly bear population in the GYE. As of 2014, there is only one active sheep allotment within the PCA, on the Caribou-Targhee National Forest.

The mandatory restriction on creating new livestock allotments and the voluntary phasing out of livestock allotments with recurring conflicts further ensure that the PCA will continue to function as source habitat. Although it is possible to reopen closed allotments, such an action would be subject to NEPA and the majority of allotments would have a low probability of reopening because the rationale behind closing them is still applicable (*e.g.,* limited forage). Livestock allotments do not currently constitute a threat to the GYE grizzly bear DPS. Additionally, because there will continue to be no net increase above 1998 levels in cattle or sheep allotments allowed on public lands inside the PCA, we do not expect that livestock allotments inside the PCA will constitute a threat in the foreseeable future.

Mineral and Energy Development: Management of oil, gas, and mining are tracked as part of the developed site standard (YES 2016a, pp. 64–67). There were no active oil and gas leases inside the PCA as of 1998 (USDA FS 2006a, p. 209). Based on Forest Plan direction, there are approximately 243 km^2 (94 mi^2) of secure habitat that could allow surface occupancy for oil and gas projects within the PCA (USDA FS 2006a, figures 48 and 96). This comprises less than 4 percent of all suitable habitat within the PCA. Additionally, 1,354 preexisting mining claims were located in 10 of the subunits inside the PCA (YES 2016b, Appendix E), but only 28 of these mining claims had operating plans. These operating plans are included in the 1998 developed site baseline.

Under the conditions of the 2016 Conservation Strategy, any new oil, gas, or mineral project will be approved only if it conforms to secure habitat and developed site standards (USFWS 2007*b,* pp. 5–6; YES 2016a, pp. 61–67). For instance, any oil, gas, or mineral project that reduces the amount of secure habitat permanently will have to provide replacement secure habitat of similar habitat quality (based on our scientific understanding of grizzly bear habitat), and any change in developed sites will require mitigation equivalent to the type and extent of the impact, and such mitigation must be in place before project initiation or be provided concurrently with project development as an integral part of the project plan (YES 2016a, p. 62). For projects that temporarily change the amount of secure habitat, only one project is

allowed in any subunit at any time (YES 2016a, p. 63). Mitigation of any project will occur within the same subunit and will be proportional to the type and extent of the project (YES 2016a, p. 62). In conclusion, because any new mineral or energy development will continue to be approved only if it conforms to the secure habitat and developed site standards set forth in the 2016 Conservation Strategy, we do not expect that such development inside the PCA will constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

Recreation: At least 3 million people visit and recreate in the National Parks and National Forests of the GYE annually (USDA FS 2006a, pp. 176, 184; Cain 2014, p. 46; Gunther 2014, p. 47). Based on past trends, visitation and recreation are expected to increase in the future. For instance, YNP has shown an approximate 15 percent increase in the number of people visiting each decade since the 1930s (USDA FS 2006a, p. 183); however, the number of people recreating in the backcountry there has remained relatively constant from the 1970s through 2010s (Gunther 2014, p. 47). The concern related to increased recreation is that it may increase the probability of grizzly bear-human encounters, with subsequent increases in human-caused mortality (Mattson *et al.* 1996, p. 1014).

Recreation in the GYE can be divided into six basic categories based on season of use (winter or all other seasons), mode of access (motorized or non-motorized), and level of development (developed or dispersed) (USDA FS 2006a, p. 187). Inside the PCA, the vast majority of lands available for recreation are accessible through non-motorized travel only (USDA FS 2006a, p. 179). Motorized recreation during the summer, spring, and fall inside the PCA will be limited to existing roads as per the standards in the 2016 Conservation Strategy that restrict increases in roads or motorized trails. Current and projected levels of non-motorized recreation, including mountain biking, do not occur at a level that requires limitations. Recreation at developed sites such as lodges, downhill ski areas, and campgrounds will be limited by the developed sites habitat standard described in the 2016 Conservation Strategy. Ongoing I&E efforts are an important contributing factor to successful grizzly bear conservation and will continue under the 2016 Conservation Strategy (YES 2016a, pp. 92–95). The number and capacity of existing developed sites on Federal lands has not increased from the 1998 baseline and will not increase once delisting occurs. For a more complete discussion of projected increases in recreation in the GYE National Forests, see the Final Environmental Impact Statement for the Forest Plan Amendment for Grizzly Bear Habitat Conservation for the GYE National Forests (USDA FS 2006a, pp. 176–189).

In conclusion, because the few motorized access routes inside the PCA will not increase, because the number and capacity of developed sites on public lands within the PCA will not increase, and because the National Parks and National Forests within the PCA will continue to educate visitors on their lands about how to recreate safely in bear country and avoid grizzly bear-human conflicts, the current level of recreation does not currently constitute a threat to the GYE grizzly bear DPS, and we do not expect recreation to constitute a threat in the foreseeable future.

Snowmobiling: Snowmobiling has the potential to disturb bears while in their dens and after emergence from their dens in the spring. Because grizzly bears are easily awakened in the den (Schwartz *et al.* 2003, p. 567) and have been documented abandoning den sites after seismic disturbance (Reynolds *et al.* 1986, p. 174), the potential impact from snowmobiling should be considered. We found no studies in the peer-reviewed literature documenting the effects of snowmobile use on any denning bear species, and the information that is available is anecdotal in nature (USFWS 2002, entire; Hegg *et al.* 2010, entire).

Disturbance in the den could result in increased energetic costs (increased activity and heart rate inside the den) and possibly den abandonment, which, in theory, could ultimately lead to a decline in physical condition of the individual or even cub mortality (Swenson *et al.* 1997, p. 37; Graves and Reams 2001, p. 41). Although the potential for this type of disturbance while in the den certainly exists, Reynolds *et al.* (1986, p. 174) found that grizzly bears denning within 1.4 to 1.6 km (0.9 to 1.0 mi) of active seismic exploration and detonations moved around inside their dens but did not leave them. Harding and Nagy (1980, p. 278) documented two instances of den abandonment during fossil fuel extraction operations. One bear abandoned its den when a seismic vehicle drove directly over the den (Harding and Nagy 1980, p. 278). The other bear abandoned its den when a gravel mining operation literally destroyed the den (Harding and Nagy 1980, p. 278). Reynolds *et al.* (1986, entire) also examined the effects of tracked vehicles and tractors pulling sledges. In 1978, there was a route for tractors and tracked vehicles within 100 m (328 ft) of a den inhabited by a female with three yearlings. This family group did not abandon their den at any point (Reynolds *et al.* 1986, p. 174). Reynolds *et al.* (1986, p. 174) documented one instance of possible den abandonment due to detonations for seismic testing within 200 m of a den. This bear was not marked, but an empty den was reported by seismic crews.

Swenson *et al.* (1997, entire) monitored 13 different grizzly bears for at least 5 winters each and documented 18 instances of den abandonment, 12 of which were related to human activities. Four of these instances were hunting related (*i.e.,* gunshots fired within 100 m (328 ft) of the den), two occurred after ''forestry activity *at* the den site,'' one had moose and dog tracks within 10 m (33 ft) of a den, one had dog tracks *at* the den site, one had ski tracks within 80 to 90 m (262 to 295 ft) from a den, one had an excavation machine working within 75 m (246 ft) of a den, and two were categorized as ''human related'' without further details (Swenson *et al.* 1997, p. 37). Swenson *et al.* (1997) found that most den abandonment (72 percent) occurred early in the season before pregnant females give birth. However, there still may be a reproductive cost of these early den abandonments: 60 percent (sample size of 5) of female bears that abandoned a den site before giving birth lost at least one cub whereas only 6 percent (sample size of 36) of pregnant females that did not abandon their dens lost a cub in or near their den (Swenson *et al.* 1997, p. 37). In the GYE, the one documented observation of snowmobile use at a known den site found the bear did not abandon its den, even though snowmobiles were operating directly on top of it (Hegg *et al.* 2010, p. 26). We found no records of litter abandonment by grizzly bears in the lower 48 States due to snowmobiling activity. Additionally, monitoring of den occupancy for 3 years on the Gallatin National Forest in Montana did not document any den abandonment (Gallatin NF 2006, entire).

In summary, the available data about the potential for disturbance while denning and den abandonment from nearby snowmobile use are extrapolated from studies examining the impacts of other human activities and are identified as ''anecdotal'' in nature (Swenson *et al.* 1997, p. 37), with sample sizes so small they cannot be legitimately applied to assess population-level impacts (in their entirety: Harding and Nagy 1980;

Reynolds *et al.* 1986; Hegg *et al.* 2010). Because there are no data or information suggesting snowmobile use in the GYE is negatively affecting the grizzly bear population, or even individual bears, we determine that snowmobiling does not constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future. Yet, because the potential for disturbance and impacts to reproductive success exists, monitoring will continue to support adaptive management decisions about snowmobile use in areas where disturbance is documented or likely to occur.

Vegetation Management: Vegetation management occurs throughout the GYE on lands managed by the USFS and NPS. Vegetation management projects typically include timber harvest, thinning, prescribed fire, and salvage of burned, diseased, or insect-infested stands. If not implemented properly, vegetation management programs can negatively affect grizzly bears by: (1) Removing hiding cover; (2) disturbing or displacing bears from habitat during the logging period; (3) increasing grizzly bear-human conflicts or mortalities as a result of unsecured attractants; and (4) increasing mortality risk or displacement due to new roads into previously roadless areas and/or increased vehicular use on existing restricted roads, especially if roads remain open to the public after vegetation management is complete.

Conversely, vegetation management may result in positive effects on grizzly bear habitat once the project is complete, provided key habitats such as riparian areas and known food production areas are maintained or enhanced. For instance, tree removal for thinning or timber harvest and prescribed burning can result in localized increases in bear foods through increased growth of grasses, forbs, and berry-producing shrubs (Zager *et al.* 1983, p. 124; Kerns *et al.* 2004, p. 675). Vegetation management may also benefit grizzly bear habitat by controlling undesirable invasive species, improving riparian management, and limiting livestock grazing in important food production areas.

Changes in the distribution, quantity, and quality of cover are not necessarily detrimental to grizzly bears as long as they are coordinated on a BMU or subunit scale to ensure that grizzly bear needs are addressed throughout the various projects occurring on multiple jurisdictions at any given time. Although there are known, usually temporary, impacts to individual bears from timber management activities, these impacts have been adequately mitigated using the Interagency Grizzly Bear Guidelines in place since 1986, and will continue to be managed at levels acceptable to the grizzly bear population under the 2016 Conservation Strategy. Therefore, we do not expect that vegetation management inside the PCA will constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

Climate Change: The effects of climate change may result in a number of changes to grizzly bear habitat, including a reduction in snowpack levels, which may shorten the denning season (Leung *et al.* 2004, pp. 93–94), shifts in denning times (Craighead and Craighead 1972, pp. 33–34; Van Daele *et al.* 1990, p. 264; Haroldson *et al.* 2002, pp. 34–35), shifts in the abundance and distribution of some natural food sources (Rodriguez *et al.* 2007, pp. 41–42), and changes in fire regimes (Nitschke and Innes 2008, p. 853; McWethy *et al.* 2010, p. 55). Most grizzly bear biologists in the United States and Canada do not expect habitat changes predicted under climate change scenarios to directly threaten grizzly bears (Servheen and Cross 2010, p. 4). These effects may even make habitat more suitable and food sources more abundant. However, these ecological changes may affect the timing and frequency of grizzly bear-human interactions and conflicts (Servheen and Cross 2010, p. 4) and are discussed below under *Factor E* (*Other Natural or Manmade Factors Affecting Its Continued Existence*).

Habitat Fragmentation: The GYE grizzly bear population is currently a contiguous population across its range, and there are no data to indicate habitat fragmentation within this population is occurring. Although currently not occurring, habitat fragmentation can cause loss of connectivity and increase human-caused mortalities, and thus is a potential threat to grizzly bears. To prevent habitat fragmentation and degradation, the evaluation of all highway construction projects in suitable habitat on Federal lands throughout the GYE DMA will continue to include the impacts of the project on grizzly bear habitat connectivity. This evaluation would go through an open and public planning process (USFWS 2007*b,* pp. 38–41; YES 2016a, pp. 82–83). By identifying areas used by grizzly bears, officials can mitigate potential impacts from road construction both during and after a project. Federal agencies will continue to identify important crossing areas by collecting information about known bear crossings, bear sightings, ungulate road mortality data, bear home range analyses, and locations of game trails.

Potential advantages of this data collection requirement include reduction of grizzly bear mortality due to vehicle collisions, access to seasonal habitats, maintenance of traditional dispersal routes, and decreased risk of fragmentation of individual home ranges. For example, work crews will place temporary work camps in areas with lower risk of displacing grizzly bears, and food and garbage will be kept in bear-resistant containers. Highway planners will incorporate warning signs and crossing structures such as culverts or underpasses into projects when possible to facilitate safe highway crossings by wildlife. Additionally, the conflict prevention, response, and outreach elements of the 2016 Conservation Strategy play an important role in preventing habitat fragmentation by keeping valleys that are mostly privately owned from becoming mortality sinks to grizzly bears attracted to human sources of foods. In conclusion, because these activities that combat habitat fragmentation will continue to occur under the 2016 Conservation Strategy, we do not expect that fragmentation within the GYE grizzly bear DPS boundaries will constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

Habitat Management Outside the Primary Conservation Area

In suitable habitat outside of the PCA within the DPS boundaries, the USFS, BLM, and State wildlife agencies will monitor habitat and population criteria to prevent potential threats to habitat, ensuring that the measures of the Act continue to be unnecessary (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 2–3; MFWP 2013, p. 5; USDA FS 2006a, pp. 44–45; WGFD 2016, p. v; YES 2016a, pp. 1–12). Factors impacting suitable habitat outside of the PCA in the future are similar to those inside the PCA and may include projects that involve road construction, livestock allotments, developed sites, and increased human-caused grizzly bear mortality risk.

Of the 22,783 km^2 (8,797 mi^2 or 5.6 million acres) of suitable habitat outside of the PCA within the DPS boundaries, the USFS manages 17,292 km^2 (6,676 mi^2), or 76 percent. Of the 76 percent of suitable habitat outside of the PCA but within the DMA that the USFS manages, nearly 80 percent (13,685 km^2 (5,284 mi^2)) is Designated Wilderness (6,799 km^2 (2,625 mi^2)), Wilderness Study Area (WSA) (708 km^2 (273 mi^2)), or Inventoried Roadless Area (IRA) (6,179

km² (2,386 mi²)). These designations provide regulatory mechanisms outside of the Act and the 2016 Conservation Strategy that protect grizzly bear habitat from new road construction, new oil and gas development, new livestock allotments, and timber harvest. This large area of widely distributed habitat allows for continued population expansion and provides additional resiliency to environmental change.

Specifically, the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*) does not allow for timber harvest, new road construction, new livestock allotments, new developed sites, and new mining claims in designated Wilderness areas (6,799 km² (2,625 mi²)), with the exception of valid existing rights. This secure suitable habitat is biologically significant to the GYE grizzly bear DPS because it allows for population expansion into these areas that are minimally affected by humans. If preexisting valid mining claims are pursued, the plans of operation are subject to reasonable regulation to protect wilderness values with mitigation to offset potential impacts from development.

Wilderness Study Areas (WSAs) (Wilderness Study Act of 1977) have been designated by Congress as areas having wilderness characteristics and warranting further study by Federal land management agencies (*e.g.,* USFS or BLM) and consideration by Congress as formally designated Wilderness. Individual National Forests manage the 708 km² (273 mi²) of WSAs to maintain their wilderness characteristics, generally until Congress acts to either designate them as permanent Wilderness or release them to multiple use management. This generally means that individual WSAs are protected from timber harvest, new road construction, new livestock allotments, and new developed sites by the legislation creating them, subject to valid existing rights. If mining claims are pursued, the plans of operation are subject to reasonable regulations to protect wilderness values with mitigation to offset potential impacts from development. Existing uses at the time of creation of the WSAs are generally allowed to continue so long as the wilderness characteristics of the area are maintained.

Inventoried Roadless Areas (IRAs) currently provide 4,891 km² (1,888 mi²) of secure habitat for grizzly bears outside of the PCA within the DPS boundaries. This amount of secure habitat is less than the total area contained within IRAs (6,179 km² (2,386 mi²)) because some motorized use occurs due to roads that existed before the area was designated as roadless. The 2001 Roadless Areas Conservation Rule (66 FR 3244, January 12, 2001; hereafter referred to as the ''Roadless Rule'') prohibits new road construction, road re-construction, and commercial timber harvest in IRAs. If mining claims are pursued, the plans of operation are subject to reasonable regulations to protect roadless characteristics with mitigation to offset potential impacts from development. Motorized roads and trails may exist within IRAs subject to forest travel management plans. Potential changes in the management of these areas are not anticipated because the Roadless Rule was upheld by the Tenth Circuit Court of Appeals in 2011. (See *Wyoming* v. *USDA,* 661 F.3d 1209 (10th Cir. 2011).)

Based on the amount of Wilderness, WSA, and IRA, an estimated 71 percent (12,396 of 17,291 km² (4,786 of 6,676 mi²)) of suitable habitat outside the PCA on USFS lands within the DPS is currently secure habitat and is likely to remain secure habitat. Upon delisting of the GYE grizzly bear, the USFS will evaluate GYE grizzly bear management as a Regional Forest Sensitive Species, and a determination of whether this status is warranted will be made at that time (USDA FS 2005). The USFS will consider the GYE grizzly bear as a potential species of conservation concern during any plan revision within the range of the GYE grizzly bear as required by FSH 1909.12 Ch. 10, 12.52(d)(2)(b), which requires consideration for any species that was removed from the Federal lists of endangered and threatened species within the past 5 years.

Additional protections occur on suitable habitat on Federal (BLM and NPS) and Tribal lands outside of the PCA but inside the DMA. The BLM manages an additional 22 percent (5,064 km² (1,955 mi²)) of suitable habitat outside of the PCA. Upon delisting of the GYE grizzly bear, the BLM in Idaho, Montana, and Wyoming will classify the grizzly bear as a Sensitive Species in the GYE for at least 5 years post-delisting. Grizzly bears and their habitats on BLM lands will then be managed consistent with Manual 6840 (BLM 2008, entire). GTNP manages 837 km² (323 mi²) of suitable habitat outside of the PCA. Protections for grizzly bears throughout NPS lands, including but not limited to seasonal area closures and food storage orders, are provided through the National Park compendium (GTNP and JDR 2016, pp. 6, 13, 21–22). The Eastern Shoshone and Northern Arapaho Tribes manage the 1,360 km² (525 mi²) of suitable habitat within the boundaries of the Wind River Reservation (WRR), all of which is outside the PCA. The Tribes' Grizzly Bear Management Plan (Eastern Shoshone and Northern Arapaho Tribes 2009) will facilitate grizzly bear occupancy in areas of suitable habitat and allow grizzly bears access to high-elevation whitebark pine and army cutworm moth aggregation sites. The WRR Forest Management Plan calls for no net increase in roads in the Wind River Roadless Area and the Monument Peak area of the Owl Creek Mountains. In the remaining lands occupied by grizzly bears, open road densities of 1.6 km/km² (1 mi/mi²) or less will be maintained (Eastern Shoshone and Northern Arapaho Tribes 2009, p. 11).

Federal, State, and Tribal agencies are committed to managing habitat so that the GYE grizzly bear DPS remains recovered and is not likely to become endangered throughout all or a significant portion of its range in the foreseeable future (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 2–3; USDA FS 2006b, entire; Eastern Shoshone and Northern Arapaho Tribes 2009, p. 11; MFWP 2013, p. 6; YNP 2014b, p. 18; GTNP and JDR 2016, p. 3; WGFD 2016, p. v; YES 2016a, pp. 54–85). In suitable habitat outside of the PCA, restrictions on human activities are more flexible, but the USFS, BLM, and Tribal and State wildlife agencies will still carefully manage these lands, monitor bear-human conflicts in these areas, and respond with management as necessary to reduce such conflicts to account for the complex needs of both grizzly bears and humans (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 16–17; USDA FS 2006b, pp. A1–A27; Eastern Shoshone and Northern Arapaho Tribes 2009, pp. 9–11; MFWP 2013, pp. 53–59; WGFD 2016, pp. 20–25; YES 2016a, pp. 86–91).

By and large, habitat management on Federal public lands is directed by Federal land management plans, not State management plans. However, the three State grizzly bear management plans recognize the importance of areas that provide security for grizzly bears in suitable habitat outside of the PCA within the DPS boundaries on Federal lands. For example, the Montana and Wyoming plans recommend limiting average road densities to 1.6 km/2.6 km² (1 mi/mi²) or less in these areas (MFWP 2013, pp. 37–39; WGFD 2016, p. 19). Both States have similar standards for elk habitat on State lands and note that these levels of motorized access benefit a variety of wildlife species while maintaining reasonable public access. Similarly, the Idaho State plan recognizes that management of motorized access outside the PCA

should focus on areas that have road densities of 1.6 km/2.6 km² (1 mi/mi²) or less. The area most likely to be occupied by grizzly bears outside the PCA in Idaho is on the Caribou-Targhee National Forest. The 1997 Targhee Forest Plan includes motorized access standards and management prescriptions outside the PCA that provide for long-term security in 59 percent of existing secure habitat outside of the PCA (USDA FS 2006a, pp. 78, 109).

In 2004, there were roughly 150 active cattle allotments and 12 active sheep allotments in suitable habitat outside the PCA within the DPS boundaries (USDA FS 2004, p. 129). The Targhee National Forest closed two of these sheep allotments in 2004, and there have not been any new allotments created since then (USDA FS 2006a, p. 168; Landenburger 2014, *in litt.*). The USFS is committed to working with willing permittees to retire allotments with recurring conflicts that cannot be resolved by modifying grazing practices (USDA FS 2006b, p. 6). Although conflicts with livestock have the potential to result in mortality for grizzly bears, the 2016 Conservation Strategy's specific total mortality limits will preclude population-level impacts. The 2016 Conservation Strategy directs the IGBST to monitor and spatially map all grizzly bear mortalities (both inside and outside the PCA), causes of death, and the source of the problem, and alter management to maintain a recovered population and prevent the need to relist the population under the Act (YES 2016a, p. 48).

There are over 500 developed sites on the five National Forests in the areas identified as suitable habitat outside the PCA within the DPS boundaries (USDA FS 2004, p. 138). While grizzly bear-human conflicts at developed sites on public lands do occur, the most frequent reason for management removals are conflicts on private lands (Servheen *et al.* 2004, p. 21). Existing USFS food storage regulations for these areas will continue to minimize the potential for grizzly bear-human conflicts through food storage requirements, outreach, and education. The number and capacity of developed sites will be subject to management direction established in Forest Plans. Should the IGBST determine developed sites on public lands are related to increases in mortality beyond the sustainable limits discussed above, managers may choose to close specific developed sites or otherwise alter management in the area in order to maintain a recovered population and prevent the need to relist the population under the Act. Due to the USFS's commitment to manage National Forest lands in the GYE to maintain a recovered population (USDA FS 2006b, pp. iii, A–6; YES 2016a, pp. 54–83), we do not expect livestock allotments or developed sites in suitable habitat outside of the PCA to reach densities that are likely to be a threat to the GYE grizzly bear DPS in the foreseeable future.

According to current Forest Plan direction, less than 19 percent (3,213 km² (1,240 mi²)) of suitable habitat outside the PCA within the DPS boundaries on USFS land allows surface occupancy for oil and gas development, and 17 percent (3,967 km² (1,532 mi²)) has both suitable timber and a management prescription that allows scheduled timber harvest. The primary impacts to grizzly bears associated with timber harvest and oil and gas development are increases in road densities, with subsequent increases in human access, grizzly bear-human encounters, and human-caused grizzly bear mortalities (McLellan and Shackleton 1988, pp. 458–459; McLellan and Shackleton 1989, pp. 377–379; Mace *et al.* 1996, pp. 1402–1403). Although seismic exploration associated with oil and gas development or mining may disturb denning grizzly bears (Harding and Nagy 1980, p. 278; Reynolds *et al.* 1986, pp. 174–175), actual den abandonment is rarely observed, and there has been no documentation of such abandonment by grizzly bears in the GYE. Additionally, only a small portion of this total land area will contain active projects at any given time, if at all. For example, among the roughly 3,967 km² (1,532 mi²) identified as having both suitable timber and a management prescription that allows timber harvest, from 2003 to 2014, an average of only 4.7 km² (1.8 mi²) was actually logged annually (Jackson 2017, *in litt.*). Similarly, although nearly 3,213 km² (1,240 mi²) of suitable habitat on National Forest lands inside the DPS boundaries allow surface occupancy for oil and gas development, there currently are no active wells inside these areas (Vaculik 2017, *in litt.*).

Ultimately, the five affected National Forests (the Beaverhead-Deerlodge, Bridger-Teton, Caribou-Targhee, Custer Gallatin, and Shoshone) will manage the number of roads, livestock allotments, developed sites, timber harvest projects, and oil and gas wells outside of the PCA in the DMA to allow for a recovered grizzly bear population. Under the National Forest Management Act of 1976, the USFS will consider all potential impacts of projects to the GYE grizzly bear population in the NEPA planning process and then ensure that activities will provide appropriate habitat to maintain the population's recovered status.

Rapidly accelerating growth of human populations in some areas outside of the PCA continues to define the limits of grizzly bear range, and will likely limit the expansion of the GYE grizzly bear population onto private lands in some areas outside the PCA. Urban and rural sprawl (low-density housing and associated businesses) has resulted in increasing numbers of grizzly bear-human conflicts with subsequent increases in grizzly bear mortality rates. Private lands account for a disproportionate number of bear deaths and conflicts (USFWS 2007*c,* figures 15 and 16). Nearly 9 percent of all suitable habitat outside of the PCA is privately owned. As private lands are developed and as secure habitat on private lands declines, State agencies will work to balance impacts from private land development (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, p. 10; MFWP 2013, p. 37; WGFD 2016, p. 15). Outside the PCA, State agencies will assist nongovernmental organizations (NGOs) and other entities to identify and prioritize potential lands suitable for permanent conservation through easements and other means as much as possible (USFWS 2007*c,* p. 54). Due to the large areas of widely distributed suitable habitat on public lands that are protected by Federal legislation and managed by agencies committed to the maintenance of a recovered grizzly bear population, we do not consider human population growth on private lands to constitute a threat to the GYE grizzly bear DPS now or in the foreseeable future.

Summary of Factor A

In summary, the following factors warranted consideration as possible threats to the GYE grizzly bear DPS under *Factor A:* Effects due to (1) motorized access management, (2) developed sites, (3) livestock allotments, (4) mineral and energy development, (5) recreation, (6) snowmobiling, (7) vegetation management, (8) climate change, and (9) habitat fragmentation. Restrictions on motorized access, developed sites, and livestock allotments ensure that they will be maintained at or below 1998 levels, a time when the population was increasing at a rate of 4 to 7 percent per year (Schwartz *et al.* 2006b, p. 48). Additionally, secure habitat will be maintained at or above 1998 levels. The primary factors related to past habitat destruction and modification have been reduced through changes in

management practices that have already been formally incorporated into regulatory documents.

Within suitable habitat, different levels of management and protection are applied to areas based on their level of importance. Within the PCA, habitat protections for grizzly bear conservation are in place across the current range where 75 percent of the females with cubs-of-the-year live most or all of the time (Schwartz *et al.* 2006a, p. 66; Haroldson 2014a, *in litt.*). For this area, the Service developed objective and measurable habitat-based recovery criteria to limit habitat degradation and human-caused mortality risk related to motorized access, developed sites, and livestock allotments (*i.e.,* the 1998 baseline). When delisting occurs, the GYE National Forests and National Parks will continue their 15-year history of implementation by legally implementing the appropriate planning documents that incorporate the 1998 baseline values as habitat standards (USDA FS 2006b, p. 26). Together, these two Federal agencies manage 98 percent of lands within the PCA and 88 percent of all suitable habitat within the DPS boundaries. As it has done for the last decade, the IGBST will continue to monitor compliance with the 1998 baseline values and will also continue to monitor grizzly bear body condition, fat levels, and diet composition. Accordingly, the PCA, which comprises 51 percent of the suitable habitat within the DPS boundaries and contains 75 percent of all females with cubs-of-the-year (Schwartz *et al.* 2006a, p. 64; Haroldson 2014a, *in litt.*), will remain a highly secure area for grizzly bears, with habitat conditions maintained at or above levels documented in 1998. Maintenance of the 1998 baseline values inside the PCA will continue to adequately ameliorate the multitude of stressors on grizzly bear habitat such that they do not become threats to the GYE grizzly bear DPS in the foreseeable future.

Suitable habitat outside the PCA provides additional ecological resiliency and habitat redundancy to allow the population to respond to environmental changes. Habitat protections specifically for grizzly bear conservation are not necessary here because other binding regulatory mechanisms are in place for nearly 60 percent of the area outside the PCA. In these areas, the Wilderness Act, the Roadless Areas Conservation Rule, and National Forest Land Management Plans limit development and motorized use. Management of individual projects on public land outside the PCA will continue to consider and minimize impacts on grizzly bear habitat. Efforts by NGOs and Tribal, State, and county agencies will seek to minimize bear-human conflicts on private lands (YES 2016a, pp. 86–91). These and other conservation measures ensure threats to the GYE grizzly bear population's suitable habitat outside the PCA will continue to be ameliorated and will not be a threat to this population's long-term persistence (USDA FS 2006b).

Other management practices on Federal lands have been changed to provide security and to maintain or improve habitat conditions for grizzly bears. All operating plans for oil and gas leases must conform to secure habitat and developed site standards, which require mitigation for any change in secure habitat. Recreation inside the GYE is limited through existing road and developed site standards. Additionally, I&E campaigns educate visitors about how to recreate safely in bear country and avoid bear-human conflicts. There are no data available on the impacts of snowmobiling on grizzly bears to suggest an effect on grizzly bear survival or recovery of the population. Although vegetation management may temporarily impact individual grizzly bears, these activities are coordinated on a BMU or subunit scale according to the Interagency Grizzly Bear Guidelines to mitigate for any potentially negative effect. As a result of vegetation management, there may also be positive effects on grizzly bears where key habitats are maintained or enhanced. The habitat changes that are predicted under climate change scenarios are not expected by most grizzly bear biologists to directly threaten grizzly bears. The potential for changes in the frequency and timing of grizzly bear-human interactions is discussed below under *Factor E.* Finally, there are no data to indicate that habitat fragmentation is occurring within the GYE.

In summary, the factors discussed under *Factor A* continue to occur across the current range of the GYE grizzly bear population but are sufficiently ameliorated so they affect only a small proportion of the population. Despite these factors related to habitat, the population has increased and stabilized while its current range has expanded. Therefore, based on the best available information and on continuation of current regulatory commitment, we do not consider the present or threatened destruction, modification, or curtailment of its habitat or range to constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

B and C. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes; Disease or Predation

Factors B and C require the Service to consider overutilization, disease, or predation affecting the continued existence of a species. In addition to disease and natural predation, we consider here human-caused mortality including legal hunting, illegal kills (see *Glossary*), defense of life and property mortality, accidental mortality, and management removals.

Excessive human-caused mortality, including ''indiscriminate illegal killing'' and management removals, was the primary factor contributing to grizzly bear decline during the 19th and 20th centuries (Leopold 1967, p. 30; Koford 1969, p. 95; Servheen 1990, p. 1; Servheen 1999, pp. 50–52; Mattson and Merrill 2002, pp. 1129, 1132; Schwartz *et al.* 2003, p. 571), eventually leading to their listing as a threatened species in 1975 (40 FR 31734, July 28, 1975). Grizzly bears were seen as a threat to livestock and human safety and, therefore, an impediment to westward expansion. Both the Federal Government and most early settlers were dedicated to eradicating large predators. Grizzly bears were shot, poisoned, trapped, and killed wherever humans encountered them (Servheen 1999, p. 50). By the time grizzly bears were listed under the Act in 1975, there were only a few hundred remaining in the lower 48 States in less than 2 percent of their former range (USFWS 1993, pp. 8–10).

Human-Caused Mortality

From 1980 to 2002, 66 percent (191) of the 290 known grizzly bear mortalities were human-caused (Servheen *et al.* 2004, p. 21). The main types of human-caused mortality were human site conflicts, self-defense, and illegal kills, all of which can be partially mitigated for through management actions (Servheen *et al.* 2004, p. 21). In our March 29, 2007, final rule (72 FR 14866), we report that despite these mortalities, this period corresponds to one during which the GYE grizzly bear population experienced population growth and range expansion. Since then, the IGBST has updated these demographic analyses using data from 2002–2011 (IGBST 2012, entire). Below, we evaluate human-caused mortality for 2002–2014, as it represents the most recent and best available information on the subject. For more information on the demographic vital rates for 2002–2011, please see *Population and Demographic Recovery Criteria* in the Recovery

Planning and Implementation section, above. In this section, we discuss impacts from human-caused mortality, including legal hunting, illegal kills, defense of life and property, accidental mortality, and management removals.

We define poaching as intentional, illegal killing of grizzly bears. People may kill grizzly bears for several reasons, including a general perception that grizzly bears in the area may be dangerous, frustration over livestock depredations, or to protest land-use and road-use restrictions associated with grizzly bear habitat management (Servheen *et al.* 2004, p. 21). Regardless of the reason, poaching continues to occur. We are aware of at least 22 such killings in the GYE between 2002 and 2014 (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). This constituted 7 percent of known grizzly bear mortalities from 2002 to 2014. This level of take occurred during a period when poaching was subject to Federal prosecution. We do not expect poaching to significantly increase upon implementation of this final rule because State and Tribal designation as a game animal means poaching will remain illegal and prosecutable (W.S. 23–1–101 (a)(xii)(A); MCA 87–2–101 (4); IC 36–2–1; IDAPA 13.01.06.100.01(e); Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 18–21; MFWP 2013, p. 6; Eastern Shoshone and Northern Arapahoe Tribes 2009, p. 9; WGFD 2016, p. 9; YES 2016a, pp. 104–116).

State and Federal law enforcement agents have cooperated to ensure consistent enforcement of laws protecting grizzly bears. Currently, State and Federal prosecutors and enforcement personnel from each State and Federal jurisdiction work together to make recommendations to all jurisdictions, counties, and States on uniform enforcement, prosecution, and sentencing relating to illegal grizzly bear kills. This cooperation means illegal grizzly bear mortalities are often prosecuted under State statutes instead of the Act. We have a long record of this enforcement approach being effective, and no reason to doubt its effectiveness in the absence of the Act's additional layer of Federal protections.

When this final rule becomes effective, all three affected States and the Eastern Shoshone and Northern Arapaho Tribes of the WRR will classify grizzly bears in the GYE as game animals, which cannot be taken without authorization by State or Tribal wildlife agencies (W.S. 23–1–101(a)(xii)(A); W.S. 23–3–102(a); MCA 87–2–101(4); MCA 87–1–301; MCA 87–1–304; MCA 87–5–302; IC 36–2–1; IDAPA 13.01.06.100.01(e); IC 36–1101(a); Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 18–21; MFWP 2013, p. 6; Eastern Shoshone and Northern Arapahoe Tribes 2009, p. 9; WGFD 2016, p. 9; YES 2016a, pp. 104–116). In other words, it will still be illegal for private citizens to kill grizzly bears unless it is in self-defense (as is currently allowed under the Act's protections), or if they have a hunting license issued by State or Tribal wildlife agencies.

In addition, in the Montana portion of the DPS, a grizzly bear may be killed if it is caught in the act of attacking or killing livestock (87–6–106 MCA). With respect to this exception, there must be injured or dead livestock associated with any grizzly bear killed in defense of livestock in Montana. There are no documented cases of livestock owners or herders actually observing a grizzly bear depredating on livestock since records began to be kept in 1975. Before that time, it would have been legal for a livestock operator to kill a grizzly bear just for being present. A similar exception that occurs in the Idaho portion of the DPS allows a grizzly bear to be killed if it is ''molesting or attacking livestock or domestic animals'' (Senate Bill 1027: Section 7: 36–1107(d)). Because Idaho contains only 6.6 percent of the DMA and has experienced low numbers of conflicts and management removals from 2002 to 2014 (9.9 and 0.3 per year, respectively, inside the DMA), we do not expect Idaho Senate Bill 1027 to be a significant source of mortality to the GYE grizzly bear.

The States will continue to enforce, prosecute, and sentence poachers as they do for any game animal such as elk, black bears, and cougars (W.S. 23–3–102(d); W.S. 23–6–202; W.S. 23–6–206; W.S. 23–6–208; MCA 87–6–301; IC 36–1404). Although it is widely recognized that poaching still occurs, this illegal source of mortality is not significant enough to hinder population stability for the GYE grizzly bear population (IGBST 2012, p. 34) or range expansion (Pyare *et al.* 2004, pp. 5–6; Bjornlie *et al.* 2014a, p. 184).

I&E campaigns (described in detail in *Factor E*) have a long record of implementation, have helped minimize the potential threat of poaching and will continue after delisting under the 2016 Conservation Strategy. More specifically, these programs address illegal killing by working to change human perceptions and beliefs about grizzly bears, and lack of tolerance to some restrictions on use of Federal lands that are designed for grizzly bear protection (Servheen *et al.* 2004, p. 27). To address the concerns of user groups who have objections to land use restrictions that accommodate grizzly bears, Federal and State agencies market the benefits to multiple species of restricting motorized access. For example, both Montana and Wyoming have recommendations for elk habitat security similar to those for grizzly bears (less than 1.6 km/2.6 km^2 (1 mi/mi^2)). This level of motorized access meets the needs of a variety of wildlife species, while maintaining reasonable opportunities for public access. I&E programs also reduce the threat of poaching and defense kills by teaching people about bear behavior and ecology so that they can avoid encounters and conflicts or respond appropriately if encounters do occur. In this way, we can correct common misconceptions and lessen the perceived threat grizzly bears pose. Additionally, I&E programs foster relationships and build trust between the general public and the government agencies implementing them by initiating communication and dialogue.

From 2002 to 2014, 31 percent (97) of human-caused grizzly bear mortalities in the GYE were self-defense or defense of other persons kills (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). This type of grizzly bear mortality is currently allowed under regulations issued under the provisions of section 4(d) of the Act (50 CFR 17.40(b)). These grizzly bear mortalities occurred primarily with elk hunters on public lands during the fall, but also at other times and locations (IGBST 2009, p. 18). These self-defense situations with elk hunters occur during surprise encounters, at hunter-killed carcasses or gut piles, or when packing out carcasses. Federal and State agencies have many options to potentially reduce conflicts with hunters (IGBST 2009, pp. 21–31), but self-defense mortalities will always be a reality when conserving a species that is capable of killing humans. By promoting the use of bear spray and continuing I&E programs pertaining to food and carcass storage and retrieval, many of these grizzly bear deaths can be avoided. Through its enabling legislations, the NPS authorizes an elk reduction program in GTNP. Elk hunters in GTNP are required to carry bear spray in an accessible location, thus reducing the potential for an encounter that results in grizzly bear mortality. Outside GTNP, carrying bear spray is strongly encouraged through hunter education programs and other I&E materials.

Another primary source of human-caused mortality is agency removal of conflict bears following grizzly bear-

human conflicts. Between 2002 and 2014, agency removals resulted in 135 mortalities, accounting for 43 percent of human-caused mortalities. This type of grizzly bear mortality is allowed under the Act through a section 4(d) rule (50 CFR 17.40(b)). While lethal to the individual grizzly bears involved, these removals promote conservation of the GYE grizzly bear population by minimizing illegal killing of bears, providing an opportunity to educate the public about how to avoid conflicts, and promoting tolerance of grizzly bears by responding promptly and effectively when bears pose a threat to public safety or repeatedly depredate livestock.

Conflicts at developed sites (on either public or private lands) were responsible for 90 of the 135 agency removals between 2002 and 2014. These conflicts usually involve attractants, such as garbage, human foods, pet/livestock/wildlife foods, livestock carcasses, and wildlife carcasses, but also are related to attitudes, understanding, and tolerance toward grizzly bears. Mandatory food storage orders on public lands decrease the change of conflicts while State and Federal I&E programs reduce grizzly bear-human conflicts on both private and public lands by educating the public about potential grizzly bear attractants and how to store them properly. Accordingly, the majority of grizzly bear budgets of the agencies responsible for implementing the 2016 Conservation Strategy and managing the GYE grizzly bear population post-delisting is for grizzly bear-human conflict management, outreach, and education. To address public attitudes and knowledge levels, I&E programs present grizzly bears as a valuable public resource while acknowledging the potential dangers associated with them and ways to avoid conflicts (for a detailed discussion of I&E, see *Factor E,* below). These outreach programs have been successful, as evidenced by a 4.2 to 7.6 percent per year population growth rate from 1983 to 2002 (Harris *et al.* 2006, p. 48) and a relatively flat grizzly bear population trajectory since 2002, despite large increases in people living and recreating in the GYE over the last 3 decades. I&E programs are integral components of the 2016 Conservation Strategy and will continue to be implemented by all partners whether the GYE grizzly bear is listed or not (YES 2016a, pp. 92–95).

Agency removals due to grizzly bear conflicts with livestock accounted for nearly 33 percent (45/135) of agency removals (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). Only 1 of these 45 mortalities occurred inside the PCA where several measures to reduce livestock conflicts are in place. The USFS phases out sheep allotments within the PCA as opportunities arise and, currently, only one active sheep allotment remains inside the PCA (USDA FS 2006a, p. 167; Landenburger 2014, *in litt.*). The USFS also has closed sheep allotments outside the PCA to resolve conflicts with species such as bighorn sheep as well as grizzly bears. Additionally, the alternative chosen by the USFS during its NEPA process to amend the five National Forest plans for grizzly bear habitat conservation includes direction to resolve recurring conflicts on livestock allotments through retirement of those allotments with willing permittees (USDA FS 2006b, pp. 16–17; YES 2016a, pp. 67–68). Livestock grazing permits include special provisions regarding reporting of conflicts, proper food storage and attractant storage procedures, and carcass removal. The USFS monitors compliance with these special provisions associated with livestock allotments annually (Servheen *et al.* 2004, p. 28). We consider these measures effective at reducing this threat, as evidenced by the rarity of livestock depredation removals inside the PCA. Upon delisting, the USFS will continue to implement these measures that minimize grizzly bear conflicts with livestock. The 2016 Conservation Strategy also recognizes that removal of individual conflict bears is sometimes required, as most livestock depredations are done by a few individuals (Jonkel 1980, p. 12; Knight and Judd 1983, p. 188; Anderson *et al.* 2002, pp. 252–253).

The 2016 Conservation Strategy and State grizzly bear management plans will guide decisions about agency removals of conflict bears post-delisting and keep this source of human-caused mortality within the total mortality limits for each age/sex class as per tables 2 and 3. The 2016 Conservation Strategy is consistent with current protocols (USDA FS 1986, pp. 53–54), emphasizing the individual's importance to the entire population. Females will continue to receive a higher level of protection than males. Location, cause of incident, severity of incident, history of the bear, health, age, and sex of the bear, and demographic characteristics are all considered in any relocation or removal action. Upon delisting, State, Tribal, and NPS bear managers will continue to coordinate and consult with each other and relevant Federal agencies (*i.e.,* USFS, BLM) about conflict bear relocation and removal decisions, but coordination with the Service during each incident will no longer be required (50 CFR 17.40). The 2016 Conservation Strategy emphasizes removal of the human cause of the conflict when possible, or management and education action to limit such conflicts (YES 2016a, pp. 86–91). In addition, the I&E team will continue to coordinate the development, implementation, and dissemination of programs and materials to aid in preventative management of bear-human conflicts. The 2016 Conservation Strategy recognizes that successful management of grizzly bear-human conflicts requires an integrated, multi-agency approach to continue to keep human-caused grizzly bear mortality within sustainable levels.

Overall, we consider agency management removals a necessary component of grizzly bear conservation. Conflict bears can become a threat to human safety and erode public support if they are not addressed. Without the support of the people that live, work, and recreate in grizzly bear country, conservation will not be successful. Therefore, we do not consider management removals a threat to the GYE grizzly bear population now, or in the foreseeable future. However, we recognize the importance of managing these sanctioned removals within sustainable levels, and Federal, Tribal, and State management agencies are committed to working with citizens, landowners, and visitors to address unsecured attractants to reduce the need for grizzly bear removals.

Humans kill grizzly bears unintentionally in a number of ways. From 2002 to 2014, there were 34 accidental mortalities and 23 mortalities associated with mistaken identification (totaling 18 percent of human-caused mortality for this time period) (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). Accidental sources of mortality during this time included road kills, electrocution, and mortalities associated with research trapping by the IGBST. For the first time since 1982, there were grizzly bear mortalities possibly associated with scientific research capture and handling in 2006. That year, four different bears died within 4 days of being captured, most likely from clostridium infections but the degraded nature of the carcasses made the exact cause of death impossible to determine. Then in 2008, two more grizzly bear mortalities suspected of being related to research capture and handling occurred. A necropsy was able to confirm the cause of death for one of these bears as a clostridium infection at the anesthesia injection site. Once the cause of death was confirmed, the IGBST changed its

handling protocol to include antibiotics for each capture (Haroldson and Frey 2009, p. 21). There has not been a research-related capture mortality since. Because of the IGBST's rigorous protocols and adaptive approach dictating proper bear capture, handling, and drugging techniques, this type of human-caused mortality is not a threat to the GYE grizzly bear population. Measures to reduce vehicle collisions with grizzly bears include removing roadkill carcasses from the road so that grizzly bears are not attracted to the roadside (Servheen *et al.* 2004, p. 28). Cost-effective mitigation efforts to facilitate safe crossings by wildlife will be voluntarily incorporated in highway construction or reconstruction projects on Federal lands within suitable grizzly bear habitat (YES 2016a, pp. 82–83).

Mistaken identification of grizzly bears by black bear hunters is a manageable source of mortality. The 2016 Conservation Strategy identifies I&E programs targeted at hunters that emphasize patience, awareness, and correct identification of targets to help reduce grizzly bear mortalities from inexperienced black bear and ungulate hunters (YES 2016a, pp. 92–95). Beginning in license year 2002, the State of Montana required that all black bear hunters pass a Bear Identification Test before receiving a black bear license (see *http://fwp.mt.gov/education/hunter/bearID/* for more information and details). Idaho and Wyoming provide a voluntary bear identification test online (MFWP 2013, p. 65; WGFD 2016, p. 16). In addition, all three States include grizzly bear encounter management as a core subject in basic hunter education courses.

The IGBST prepares annual reports analyzing the causes of conflicts, known and probable mortalities, and proposed management solutions (Servheen *et al.* 2004, pp. 1–29). The IGBST will continue to use these data to identify where problems occur and compare trends in locations, sources, land ownership, and types of conflicts to inform proactive management of grizzly bear-human conflicts. As directed by the 2016 Conservation Strategy, upon delisting, the IGBST will continue to summarize conflict bear control actions in annual reports and the YGCC will continue the YES's role reviewing and implementing management responses (IGBST 2009, entire; YGCC 2009, entire; YES 2016a, pp. 86–91). The IGBST and YGCC implemented this adaptive management approach when the GYE grizzly bear population was delisted between 2007 and 2009. After high levels of mortality in 2008, the IGBST provided management options to the YGCC about ways to reduce human-caused mortality. In fall 2009, the YGCC provided updates on what measures they had implemented since the report was released the previous spring. These efforts, conducted through I&E and State fish and game agencies, included: increased outreach on the value of bear spray; development of a comprehensive encounter, conflict, and mortality database; and increased agency presence on USFS lands during hunting season. For a complete summary of agency responses to the IGBST's recommendations, see pages 9–18 of the fall YGCC 2009 meeting minutes (YGCC 2009). Because human-caused mortality has been reduced through I&E programs (*e.g.,* bear identification education to reduce grizzly bears killed by black bear hunters as a result of mistaken identity kills) and management of bear removals (*e.g.,* reduction in livestock predation), we conclude this source of mortality does not constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

No grizzly bears have been removed from the GYE since 1975 for commercial, recreational, scientific, or educational purposes. While there have been some mortalities related to research trapping since 1975, these were accidental as discussed above. The only commercial or recreational take anticipated post-delisting is a limited, controlled hunt, discussed below.

The population has stabilized inside the DMA since 2002, with the model-averaged Chao2 population estimate for 2002–2014 being 674 (95% CI = 600–747). This stabilization over 13 years is strong evidence that the population is exhibiting density-dependent population regulation inside the DMA, and this has recently been documented (van Manen *et al.* 2016, entire). The fact that the population inside the DMA has stabilized is probably due to density-dependent effects and is further evidence that the population has achieved recovery within the DMA.

Accordingly, the agencies implementing the 2016 Conservation Strategy have decided that the population in the DMA will be managed to maintain the population around the long-term average population size for 2002–2014 of 674 (95% CI = 600–747) (using the model-averaged Chao2 population estimate), consistent with the revised demographic recovery criteria (USFWS 2017, entire) and the Tri-State Memorandum of Agreement (MOA) (Wyoming Game and Fish Commission *et al.* 2016). The population inside the DMA has stabilized at this population size, and density-dependent regulation may be a contributing factor (van Manen *et al.* 2016, entire). The model-averaged Chao2 population estimator will be used by the IGBST to annually estimate population size inside the DMA (in their entirety: Wyoming Game and Fish Commission *et al.* 2016; YES 2016a), as this currently represents the best available science. To achieve a population in the DMA that remains around the 2002–2014 average of 674, total mortality is limited to <7.6 percent for independent females when the population is at or below 674, with higher mortality limits when the population is higher than 674 (as per tables 2 and 3). A total mortality rate of 7.6 percent for independent females is the mortality level that the best available science shows results in population stability (IGBST 2012, entire). Annual estimates of population size in the DMA will be derived each fall by the IGBST from the model-averaged Chao2 estimate of females with cubs-of-the-year (*i.e.,* the model-averaged Chao2 population estimate). These annual estimates will normally vary as in any wild animal population. The annual model-averaged Chao2 population estimate for a given year within the DMA will be used to set the total mortality limits from all causes for the DMA for the following year as per tables 2 and 3. Mortalities will be managed on a sliding scale within the DMA as set forth in table 2.

When this final rule is made effective, grizzly bears will be classified as a game species throughout the GYE DPS boundaries outside National Parks and the WWR in the States of Wyoming, Montana, and Idaho (W.S. 23–1–101 (a)(xii)(A); MCA 87–2–101 (4); IC 36–2–1; IDAPA 13.01.06.100.01(e); Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 18–21; MFWP 2013, p. 6; Eastern Shoshone and Northern Arapahoe Tribes 2009, p. 9; WGFD 2016, p. 9; YES 2016a, pp. 104–116). While the States may choose to institute a carefully regulated hunt with ecosystem-wide coordinated total mortality limits (Wyoming Game and Fish Commission *et al.* 2016, p. 5; YES 2016a, p. 46), we do not expect grizzly bear trapping to occur due to public safety considerations and the precedent that there has never been public grizzly bear trapping in the modern era. The States of Montana, Idaho, and Wyoming do not permit public trapping of any bears currently, and there is no information to indicate they will begin. Public trapping is not identified as a possible management tool in any of their State management plans. Even if the States were to allow trapping in the

future, the mortality limits would apply, as described in table 3. Hunting on the WRR will be at the discretion of the Tribes and only be available to Tribal members (Title XVI Fish and Game Code, Eastern Shoshone and Northern Arapaho Tribes 2009, p. 9). The NPS will not allow grizzly bear hunting within National Park boundaries. Within the DMA (see figure 1), the NPS, the MFWP, the WGFD, the IDFG, and the Tribes of the WRR will manage total mortality to ensure all recovery criteria continue to be met.

TABLE 3—FRAMEWORK TO MANAGE MORTALITY LIMITS INSIDE THE DMA

Management framework	Background and application protocol			
1. Area within which mortality limits apply	49,928 km^2 (19,279 mi^2) DMA (see figure 1).			
2. 2016 Conservation Strategy Goal/Recovery Criteria	To ensure the continuation of a recovered grizzly bear population in accordance with the established Recovery Criteria. See *Demographic Recovery Criteria* in the Recovery Planning and Implementation section, above.			
3. Population estimator	The model-averaged Chao2 population estimator will be used as the population measurement tool for the foreseeable future. The model-averaged Chao2 population estimate for 2002–2014 was 674 (95% CI = 600–747).			
4. Mortality limit setting protocol	Each fall the IGBST will annually produce a model-averaged Chao2 population estimate for the DMA. That population estimate will be used to establish the total mortality limit percentages for each age/sex class for the following year as per #8, #9, and #10 (below).			
5. Allocation process for managed mortalities	As per the Tri-State MOA, the States* will meet annually in the month of January to review population monitoring data supplied by IGBST and collectively establish discretionary mortality within the total mortality limits per age/sex class available for regulated harvest for each jurisdiction (MT, ID, WY) in the DMA, so DMA thresholds are not exceeded. If requested, the WRR will receive a portion of the available mortality limit based on the percentage of the WRR geographic area within the DMA. Mortalities outside the DMA are the responsibility of each State and do not count against total mortality limits.			
6. State regulatory mechanisms specific to discretionary sport take	For specific State regulatory mechanisms, please see the discussion below regarding the Tri-State MOA and State regulations for ID, MT, and WY.			
7. Management review by the IGBST	A demographic review will be conducted by the IGBST every 5 to 10 years at the direction of the YGCC. This management review will assess if the management system is achieving the desired goal of ensuring a recovered grizzly bear population in accordance with recovery criteria. The management review is a science-based process that will be led by the IGBST (which includes all State and Federal agencies and the WRR Tribes) using all recent available scientific data to assess population numbers and trend against the recovery criteria. Age/sex-specific survival and reproductive rates will also be reevaluated using the most recent data to adjust total mortality levels as necessary.			
8. Total mortality limit % for independent FEMALES	Pop. Size**	≤674	675–747	>747
	Mort. %	<7.6%	9%	10%
9. Total mortality limit % for independent MALES	Pop. Size**	≤674	675–747	>747
	Mort. %	15%	20%	22%
10. Total mortality limit % for dependent young	Pop. Size**	≤674	675–747	>747
	Mort. %	<7.6%	9%	10%

*The States will confer with the NPS, the USFS, and the BLM annually and will invite representatives of both GYE National Parks, the NPS regional office, the GYE USFS Forest Supervisors, and a representative from the BLM to attend the annual meeting.
**Using the model-averaged Chao2 estimate.

The States have enacted the following regulatory mechanisms by law and regulations that address human-caused mortality, including mortality from hunting. The State regulatory mechanisms include: Grizzly Bear Management Hunting Regulations; Wyoming Game and Fish Commission Chapter 67 Grizzly Bear Management Regulation; Proclamation of the Idaho Fish and Game Relating to the Limit of the Take of Grizzly Bear in the Greater Yellowstone Ecosystem; Montana Fish, Wildlife & Parks Grizzly Bear Montana Hunting Regulations; and the Memorandum of Agreement Regarding the Management and Allocation of Discretionary Mortality of Grizzly Bears in the Greater Yellowstone Ecosystem (the Tri-State MOA) (in their entirety: Idaho Fish and Game Commission 2016; MFWP 2016; Montana Fish and Wildlife Commission Resolution, July 13, 2016, pp. 753–761; approving the Tri-State MOA; Wyoming Game and Fish Commission 2016; Wyoming Game and Fish Commission *et al.* 2016). These regulatory mechanisms include:

- Suspend all discretionary mortality inside the DMA, except if required for human safety, if the model-averaged

Chao2 population estimate falls below 600 (Montana Fish and Wildlife Commission Resolution, July 13, 2016, pp. 753–761; approving the Tri-State MOA; Tri-State MOA: Section IV(2)(c)(i), Section IV (2)(a)(i); Chapter 67 of WY Game and Commission Regulations: Section 4(c); Idaho Fish and Game Commission Proclamation: Section 2);

- Suspend grizzly bear hunting inside the DMA if total mortality limits for any sex/age class (as per tables 2 and 3) are met at any time during the year (Montana Fish and Wildlife Commission Resolution, July 13, 2016, pp. 753–761; approving the Tri-State MOA; Tri-State MOA: Section IV(2)(c), Section IV(4)(a), Section IV(6); Chapter 67 of WY Game and Commission Regulations: Section 4(d); Idaho Fish and Game Commission Proclamation: Section 5);
- Prohibit hunting of female grizzly bears accompanied by young (Montana Fish and Wildlife Commission Resolution, July 13, 2016, pp. 753–761; approving the Tri-State MOA; Tri-State MOA: Section IV(4)(b); MT State Hunting Regulations pp. 4, 7; Chapter 67 of WY Game and Commission Regulations: Section 4(e); Idaho Fish and Game Commission Proclamation: Section 4);
- In a given year, discretionary mortality will be allowed only if non-discretionary mortality does not meet or exceed total mortality limits for that year (Montana Fish and Wildlife Commission Resolution, July 13, 2016, pp. 753–761; approving the Tri-State MOA; Tri-State MOA: Section IV(2)(c), Section IV(4)(a), Section IV(6); Chapter 67 of WY Game and Commission Regulations: Section 4(d), Section 4(k); Idaho Fish and Game Commission Proclamation: Section 5); and
- Any mortality that exceeds allowable total mortality limits in any year will be subtracted from that age/sex class allowable total mortality limit for the following year to ensure that long-term mortality levels remain within prescribed limits inside the DMA (Montana Fish and Wildlife Commission Resolution, July 13, 2016; approving the Tri-State MOA; Tri-State MOA: Section IV(2)(c); Chapter 67 of WY Game and Commission Regulations: Section 4(g), Section 4(k), and Section 4(l); Idaho Fish and Game Proclamation: Section 6).

The Tri-State MOA was signed by Idaho, Montana, and Wyoming wildlife agencies in July/August 2016. In it, the three States commit to manage grizzly bears consistent with the 2007 Conservation Strategy and all revisions associated with delisting (which includes the 2016 Conservation Strategy approved by all three States), to use the best science to collectively manage grizzly bears, and to manage discretionary mortality consistent with the model-average Chao2 population estimate from 2002 to 2014. The Service believes the Tri-State MOA will be implemented because all parties have approved it. In addition to their signatures on the MOA, the States have either adopted the entire MOA or key parts of it via regulatory mechanisms. The Idaho Fish and Game Commission adopted a proclamation agreeing to the MOA mortality limits (Idaho Fish and Game Commission 2016; Trever 2017, *in litt.*). Montana adopted the Tri-State MOA by resolution (Resolution of the Montana Fish and Game Commission, July 13, 2016, pp. 753–761). Wyoming regulations require Wyoming to coordinate management of grizzly bears in the DMA through the Tri-State MOA (Wyo. Code R. Ch. 67, Section 4(k)).

The States' authorities to implement important aspects of the Tri-State MOA are set forth in Attachment B of the Tri-State MOA. These regulatory mechanisms include the authority to suspend hunting seasons, prohibit the take of females with young, and to enact emergency closures for other reasons, *e.g.,* mortality, habitat changes. State staffing and funding are expected to be consistent with the State's long-term track records of effectively managing other big game species. The Service believes the Tri-State MOA will be effective because it implements population goals, including mortality limits, set forth in the 2016 Conservation Strategy. These objectives are based on successful management criteria from the 2007 Conservation Strategy, and are largely responsible for stable to increasing populations within the GYE. The States also have a strong incentive to manage within the recovery criteria to maintain management flexibility to respond to conflict bears. As reflected in the Tri-State MOA, if the grizzly bear population estimate falls below 600, discretionary mortality (including conflict bears) is prohibited, unless necessary for human safety.

In addition to the regulatory mechanism above, the IGBST will complete a Biology and Monitoring Review to evaluate the impacts of these total mortality levels on the population and present it to the YGCC and the public if any of the following conditions are met: (1) Exceeding independent female mortality limits in 3 consecutive years, or (2) exceeding independent male mortality limits in 3 consecutive years, or (3) exceeding dependent young mortality limits in 3 consecutive years (YES 2016a, pp. 100–102). The States will coordinate via the Tri-State MOA to manage total mortalities within the DMA to be within the age/sex mortality limits as per tables 2 and 3.

The number of grizzly bears available for discretionary mortality in a given year is based on the model-averaged Chao2 population estimate inside the DMA from the previous year, the total annual allowable mortality rate (see table 2), the total annual allowable mortality numbers, and the non-discretionary mortality from the previous year. Total annual allowable mortality numbers are calculated each year by multiplying the total annual mortality rate by the size of each sex/age cohort, which varies with population size, from the previous year. Total mortality includes documented known and probable grizzly bear mortalities from all causes, including but not limited to: management removals, illegal kills, mistaken identity kills, self-defense kills, vehicle kills, natural mortalities, undetermined-cause mortalities, grizzly bear hunting, and a statistical estimate of the number of unknown/unreported mortalities (Cherry *et al.* 2002). The number of non-discretionary mortalities for independent females and males from the previous year will then be subtracted from the total number of allowable mortalities for the most recent population estimate resulting in the number of independent female and male bears available for discretionary mortality (hunting allocation or management removals). If the previous year's total mortality exceeded total allowable mortality, then any exceedance will be subtracted from allowable discretionary mortality for the current year. The example (table 4) serves to demonstrate how the expected number of bears available for hunting mortality will be calculated and the number of independent female and male bears available for hunting inside the DMA.

TABLE 4—EXAMPLE CALCULATION OF ALLOWABLE TOTAL ANNUAL MORTALITY INSIDE THE DMA AND EXPECTED NUMBER OF INDEPENDENT FEMALE AND MALE BEARS AVAILABLE FOR HUNTING INSIDE THE DMA IN 2016 BASED ON THE 2015 ESTIMATED POPULATION SIZE OF 717 AND MORTALITY THAT OCCURRED DURING 2015

	Independent females	Independent males
Size of sex/age cohort at this population size from 2015	250	250
Total annual mortality rate	9%	20%
Allowable total annual mortality number for 2016	22	50
Non-discretionary mortality from 2015 (to be subtracted)	22	19
Exceedance of total mortality resulting from discretionary actions, if any, from 2015 (to be subtracted)	3	0
Bears available for discretionary mortality (hunting or management removals) inside the DMA for 2016	0	31

This example serves to explain the process that the States will use to determine allowable discretionary mortality. State fish and wildlife agencies, or their Wildlife Commissions, have discretion to determine whether they intend to propose a grizzly bear hunting season in any year and, if so, how much discretionary mortality they will authorize to allocate to discretionary mortality while remaining within the limits that maintain a recovered population.

Other regulations, such as timing and location of hunting seasons, should seasons be implemented, would be devised by the States to minimize the possibility of exceeding total mortality limits of independent females within the DMA (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, p. 20; MFWP 2013, p. 61; WGFD 2016, p. 16).

To ensure that the distribution criterion (16 of 18 bear management units within the Recovery Zone must be occupied by females with young, with no 2 adjacent bear management units unoccupied, during a 6-year sum of observations) is maintained, the IGBST will annually monitor and report the current distribution of reproducing females. If the necessary distribution of reproducing females is not met for 3 consecutive years, the IGBST will complete a Biology and Monitoring Review to evaluate the impacts of reduced distribution of reproducing females on the population and present it to the YGCC. This Biology and Monitoring Review will consider the significance of the reduced distribution of reproducing females and make recommendations to increase their current distribution as necessary.

The Service will initiate a formal status review and could emergency re-list the GYE grizzly bear population until the formal status review is complete under any of the following conditions:

(1) If there are any changes in Federal, State, or Tribal laws, rules, regulations, or management plans that depart significantly from the specifics of population or habitat management detailed in this final rule or the 2016 Conservation Strategy that would significantly increase the threat to the GYE grizzly bear population. The Service will promptly conduct such an evaluation of any change in a State or Federal agency's regulatory mechanisms to determine if such a change represents a threat to the GYE grizzly bear population. As the Service has done for the Rocky Mountain DPS of gray wolf, such an evaluation will be documented for the record and acted upon if necessary.

(2) If the population falls below 500 in any year using the model-averaged Chao2 population estimator, or counts of females with cubs-of-the-year fall below 48 for 3 consecutive years.

(3) If fewer than 16 of 18 bear management units are occupied by females with young for 3 consecutive 6-year sums of observations. Monitoring and status review provisions are discussed in detail later in this final rule.

In areas of the GYE grizzly bear DPS outside the DMA boundaries, respective States and Tribes may establish hunting seasons independent of the total mortality limits inside the DMA. Hunting mortality outside the DMA boundary would not threaten the GYE grizzly bear DPS because total mortality limits are in place as per tables 2 and 3 for the source population within the DMA boundary.

To increase the likelihood of occasional genetic interchange between the GYE grizzly bear population and the NCDE grizzly bear population, the State of Montana has indicated they will manage discretionary mortality in this area in order to retain the opportunity for natural movements of bears between ecosystems (MFWP 2013, p. 9). Maintaining the presence of non-conflict grizzly bears in areas between the NCDE management area and the DMA of the GYE, such as the Tobacco Root and Highland Mountains, would likely facilitate periodic grizzly bear movements between the NCDE and GYE.

To ensure total mortality rates remain consistent with population objectives after delisting, the IGBST will conduct a demographic review of population vital rates (table 3, item #7) at least every 5 to 10 years for the foreseeable future. The results of these reviews will be used to make appropriate adjustments to ensure that the population remains recovered in accordance with the recovery criteria. The 5- to 10-year time interval was selected based on life-history characteristics of bears and methodologies in order to obtain estimates with acceptable levels of uncertainty and statistical rigor (Harris *et al.* 2011, p. 29).

In the period 2002–2014, 76 percent of known or probable grizzly bear mortalities in the GYE DMA (311/410) were human-caused (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). Human-caused mortalities of independent female grizzly bears have increased gradually each year; however, human-caused mortality of these females as a proportion of the estimated population size (*i.e.,* mortality rate) has remained relatively constant in the fall when bears are at an increased risk of conflicts involving hunters (van Manen 2015, *in litt.*). Overall, human-caused mortality rates have been low enough to allow the GYE grizzly bear population to increase in numbers and range (Schwartz *et al.* 2006a, pp. 64–66; Schwartz *et al.* 2006b, p. 48; Bjornlie *et al.* 2014a, p. 184). Total mortality limits and State regulations to manage within agreed-upon limits as per tables 2 and 3 will ensure that mortality will continue to be managed at levels that avoid persistent population decline. Therefore, we conclude that human-caused mortality does not constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

Disease

Although grizzly bears have been documented with a variety of bacteria

and other pathogens, parasites, and disease, fatalities are uncommon (LeFranc *et al.* 1987, p. 61) and do not appear to have population-level impacts on grizzly bears (Jonkel and Cowan 1971, pp. 31–32; Mundy and Flook 1973, p. 13; Rogers and Rogers 1976, p. 423). Researchers have found grizzly bears with brucellosis (type 4), clostridium, toxoplasmosis, canine distemper, canine parvovirus, canine hepatitis, and rabies (LeFranc *et al.* 1987, p. 61; Zarnke and Evans 1989, p. 586; Marsilio *et al.* 1997, p. 304; Zarnke *et al.* 1997, p. 474). However, based on nearly 40 years of research by the IGBST, natural mortalities in the wild due to disease have never been documented (IGBST 2005, pp. 34–35; Craighead *et al.* 1988, pp. 24–84). Based on this absence in more than 50 years of data, we conclude that mortalities due to bacteria, pathogens, or disease are negligible components of total mortality in the GYE and are likely to remain an insignificant factor in population dynamics into the foreseeable future. Therefore, we conclude that this source of mortality does not constitute a threat to the GYE grizzly bear DPS now or in the foreseeable future.

Natural Predation

Grizzly bears are occasionally killed by other wildlife. Adult grizzly bears kill dependent young, subadults, or other adults (Stringham 1980, p. 337; Dean *et al.* 1986, pp. 208–211; Hessing and Aumiller 1994, pp. 332–335; McLellan 1994, p. 15; Schwartz *et al.* 2003, pp. 571–572). This type of intraspecific killing seems to occur rarely (Stringham 1980, p. 337) and has only been observed among grizzly bears in the GYE 28 times between 1986 and 2012 (Haroldson 2014b, *in litt.*). Wolves and grizzly bears often scavenge similar types of carrion and, sometimes, will interact with each other in an aggressive manner. Since wolves were reintroduced into the GYE in 1995, we know of 339 wolf-grizzly bear interactions with 6 incidents in which wolf packs likely killed grizzly bear cubs-of-the-year and 2 incidents in which wolves likely killed adult female grizzly bears (Gunther and Smith 2004, pp. 233–236; Gunther 2014, *in litt.*). Overall, these types of aggressive interactions among grizzly bears or with other wildlife are rare and are likely to remain an insignificant factor in population dynamics into the foreseeable future. Therefore, we conclude this source of mortality does not constitute a threat to the GYE grizzly bear DPS now, or in the foreseeable future.

Summary of Factors B and C Combined

In summary, the following factors warranted consideration as possible threats to the GYE grizzly bear DPS under *Factors B and C Combined:* (1) Human-caused mortality, including legal hunting; (2) natural disease; and (3) natural predation. Both natural disease and natural predation are rare occurrences and, therefore, are not considered a threat to the GYE grizzly bear population. Human-caused mortality includes legal hunting, illegal kills, defense of life and property mortality, accidental mortality, and management removals. I&E programs reduce human-caused mortality by: (1) Changing human perceptions and beliefs about grizzly bears; (2) educating recreationists and hunters on how to avoid encounters and conflicts, how to react during a bear encounter, use of bear spray, and proper food storage; and (3) educating black bear hunters on bear identification.

Overall, from 2002 to 2014, the GYE grizzly bear population incurred an average of 23.9 human-caused mortalities per year (Haroldson 2014b, *in litt.;* Haroldson and Frey 2015, p. 26). Despite these mortalities, the GYE grizzly bear population has continued to increase in size and expand its current distribution (Pyare *et al.* 2004, pp. 5–6; Schwartz *et al.* 2006a, pp. 64–66; Schwartz *et al.* 2006b, p. 48; IGBST 2012, p. 34; Bjornlie *et al.* 2014a, p. 184). Although humans are still directly or indirectly responsible for the majority of grizzly bear deaths, this source of mortality is effectively mitigated through science-based management, monitoring, and outreach efforts. The agencies have institutionalized the careful management and monitoring of human-caused mortality through the 2016 Conservation Strategy, National Forest and National Park management plans, State grizzly bear management plans, and State wildlife commission rules and regulations (Idaho Fish and Game Commission 2016; MFWP 2016; Wyoming Game and Fish Commission 2016; Wyoming Game and Fish Commission *et al.* 2016; YES 2016a). Because a section 4(d) rule (50 CFR 17.40(b)) currently allows grizzly bears to be killed in self-defense, defense of others, or by agency removal of conflict bears, management of human-caused mortality post-delisting will not differ significantly once protections of the Act are no longer in place.

If grizzly bear hunting occurs, hunting mortality would be within the total mortality limits for independent females and males noted in tables 2 and 3 that ensure the population remains recovered within the DMA as measured by adherence to total mortality limits and annual population estimates. Hunting will not occur if other sources of mortality exceed the total mortality limits (see table 3). The States have incorporated the total mortality limits for each age/sex class based on annual IGBST model-averaged Chao2 population estimates set forth in table 2 in the Tri-State MOA and State regulations (Idaho Fish and Game Commission 2016; MFWP 2016; Wyoming Game and Fish Commission 2016; Wyoming Game and Fish Commission *et al.* 2016). The States have also implemented laws and regulations that will guide management responses to any departures from total mortality limits for independent females, independent males, and dependent young to maintain the population inside the DMA around the average population size from 2002–2014 (Idaho Fish and Game Commission 2016; MFWP 2016; Wyoming Game and Fish Commission 2016; Wyoming Game and Fish Commission *et al.* 2016). In addition, the State of Montana will manage discretionary mortality in the area between the GYE and the NCDE in order to retain the opportunity for natural movements of bears between ecosystems (MFWP 2013, p. 14).

In addition, as discussed above, the Service will initiate a status review with possible emergency re-listing pursuant to the Act if: (1) There are any changes in Federal, State, or Tribal laws, rules, regulations, or management plans that depart significantly from the specifics of population or habitat management detailed in this final rule or the 2016 Conservation Strategy that would significantly increase the threat to the GYE grizzly bear population. The Service will promptly conduct such an evaluation of any change in a State or Federal agencies change in regulatory mechanisms to determine if such a change represents a threat to the GYE grizzly bear population. As the Service has done for the Rocky Mountain DPS of gray wolf, such an evaluation will be documented for the record and acted upon if necessary; or (2) the population falls below 500 in any year using the model-averaged Chao2 population estimator, or counts of females with cubs-of-the-year fall below 48 for 3 consecutive years; or (3) fewer than 16 of 18 bear management units are occupied by females with young for 3 consecutive 6-year sums of observations.

These commitments have been implemented into regulations and ameliorate impacts related to potential commercial and recreational hunting

such that hunting will not threaten the GYE grizzly bear DPS in the foreseeable future. In addition to State laws and regulations, the IGBST will conduct a demographic review of the population vital rates every 5 to 10 years on which allowable total mortality limits are based to ensure adherence to the population objective. We consider the regulatory commitment by State and Federal agencies outlined above to reasonably ensure conservation of the GYE grizzly bear DPS.

Therefore, based on the best available scientific and commercial information, detailed State and Federal regulatory and other commitments, application of mortality management detailed in this final rule and the 2016 Conservation Strategy, and the expectation that these bear management practices will continue into the foreseeable future, we conclude that natural disease, predation, and human-caused mortality do not constitute threats to the GYE grizzly bear DPS now and are not anticipated to constitute threats in the foreseeable future.

D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine the stressors identified within the other factors as ameliorated or exacerbated by any existing regulatory mechanism or conservation effort designed to address threats to a species or pertain to the overall State management of a species. Section 4(b)(1)(A) of the Act requires that the Service take into account ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species. . . .'' We consider relevant Federal, State, and Tribal laws, regulations, and other binding legal mechanisms that may ameliorate or exacerbate any of the threats we describe in threat analyses under the other four factors or otherwise enhance the species' conservation. Our consideration of regulatory mechanisms is described in detail within the discussion of each of the threats or stressors to the species (*see* discussion under each of the other Factors).

The following existing regulatory mechanisms are specifically considered and discussed as they relate to the stressors, under the applicable Factors, affecting the GYE grizzly bear DPS. Under *Factor A:*

- 2006 Forest Plan Amendment for Grizzly Bear Habitat Conservation for the Greater Yellowstone Area National Forests,
- Wilderness Act of 1964, the 2001 Roadless Rule, and
- YNP and GTNP Compendia implemented under the National Park Service Organic Act. The Organic Act of 1916, 16 U.S.C. Section 1, created the NPS and assigned it the responsibility to manage the national parks. The Organic Act requires the NPS to manage park units to conserve scenery, natural and historic objects within parks, and wildlife, and to provide for their enjoyment in a manner that leaves them unimpaired for the enjoyment of future generations.

Under Factors B and C Combined

- State of Idaho Yellowstone Grizzly Bear Management Plan,
- Proclamation of the Idaho Fish and Game Commission Relating to the Limit of the Take of Grizzly Bear in the Greater Yellowstone Ecosystem,
- Grizzly Bear Management Plan for Southwestern Montana,
- Montana Hunting Regulations for Grizzly Bear,
- Montana Fish and Wildlife Commission Resolution approving the Tri-State MOA (July 13, 2016),
- Wyoming Grizzly Bear Management Plan,
- Wyoming Game and Fish Commission Chapter 67 Grizzly Bear Management Regulation, and
- Memorandum of Agreement Regarding the Management and Allocation of Discretionary Mortality of Grizzly Bears in the GYE.

Therefore, based on the best available information and on continuation of current regulatory commitment, we do not consider inadequate regulatory mechanisms to constitute a threat to the GYE grizzly bear DPS now or in the foreseeable future.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Factor E requires the Service to consider other natural or manmade factors affecting the continued existence of a species. Here, five other considerations warrant additional discussion regarding the GYE grizzly bear DPS: Effects due to: (1) Genetic health; (2) changes in food resources; (3) climate change; (4) catastrophic events; and (5) human attitudes toward grizzly bear conservation.

Genetic Health

The isolated nature of the GYE grizzly bear population was identified as a potential threat when listing occurred in 1975. Declines in genetic diversity are expected in isolated populations (Allendorf *et al.* 1991, p. 651; Burgman *et al.* 1993, p. 220). For the GYE grizzly bear population, decreases in genetic diversity would occur gradually over decades due to long generational time and relatively large population size (Miller and Waits 2003, p. 4338). Indicators of fitness in the GYE grizzly bear population demonstrate that the current levels of genetic diversity are capable of supporting healthy reproductive and survival rates, as evidenced by normal litter size, no evidence of disease, high survivorship, an equal sex ratio, normal body size and physical characteristics, and a relatively constant population size within the DMA (van Manen 2016a, *in litt.*). These indicators of fitness will be monitored annually for the foreseeable future. Because current levels of genetic diversity are adequate and heterozygosity values have increased slightly over the last few decades from 0.55 (Paetkau *et al.* 1998, p. 421), to 0.56 (Miller and Waits 2003, p. 4337), to 0.60 using more recent data and larger sample sizes (Haroldson *et al.* 2010, p. 7), we know there is no immediate need for new genetic material (Miller and Waits 2003, p. 4338). Heterozygosity is a measure of genetic diversity, which when low can negatively impact demographic rates and reduce the species' ability to respond to environmental change.

Effective population size is a metric used by geneticists to distinguish between total population size and the actual number of individuals available to reproduce at any given time. For example, many individuals in a population may be too young to reproduce and, therefore, are not part of the ''effective population size.'' For short-term fitness (*i.e.,* evolutionary response), the effective population size of the GYE grizzly bear population should remain above 100 animals (Miller and Waits 2003, p. 4338). In grizzly bears, Miller and Waits (2003, p. 4337) reported that an effective population size is approximately 25 to 27 percent of total population size, so an effective population size of 100 corresponds to a total population size of about 400 animals. However, reported ratios of effective population size to census size for grizzly bear populations vary widely from 0.04 to 0.6 (Paetkau *et al.* 1998; Miller and Waits 2003; Schregel *et al.* 2012). The ratio of effective population size to census size of 0.42 reported by Kamath *et al.* (2015) falls towards the upper middle of that range and most likely reflects the underestimation bias of the Chao2 population estimator.

To further ensure this minimum number of animals in the population necessary for genetic health is always maintained, the revised demographic recovery criteria as well as the 2016

Conservation Strategy established a standard to maintain the total population size above 500 animals to ensure short-term genetic fitness (YES 2016a, pp. 33–53; USFWS 2017, pp. 2–3). Recent work (Kamath *et al.* 2015, p. 5512) demonstrates that the effective population size (N_e) of the GYE population has increased from 102 (95% CI = 64–207) in 1982, to 469 (95% CI= 284–772) in 2010. The current effective population is more than four times the minimum effective population size suggested in the literature (Miller and Waits 2003, p. 4338).

While this current estimated effective population size of approximately 469 animals (Kamath *et al.* 2015, p. 5512) is adequate to maintain genetic health in this population, 1 to 2 effective migrants from other grizzly bear populations every 10 years would maintain or enhance this level of genetic diversity and, therefore, ensure genetic health in the long term (Mills and Allendorf 1996, pp. 1510, 1516; Newman and Tallmon 2001, pp. 1059–1061; Miller and Waits 2003, p. 4338) and benefit its long-term persistence (Boyce *et al.* 2001, pp. 25, 26; Kamath *et al.* 2015, p. 5517). We have defined an effective migrant as an individual that immigrates into an isolated population from a separate area, survives, breeds, and whose offspring survive.

Based on Miller and Waits (2003, p. 4338), the 2007 Conservation Strategy recommended that if no movement or successful genetic interchange was detected by 2020, grizzly bears from the NCDE would be translocated into the GYE grizzly bear population to achieve the goal of two effective migrants every 10 years (*i.e.,* one generation) to maintain current levels of genetic diversity (USFWS 2007*c,* p. 37). In light of new information in Kamath *et al.* (2015, entire) documenting stable levels of heterozygosity and a current effective population size of 469 animals (Kamath *et al.* 2015, p. 5512), the deadline of 2020 for translocation is no longer contained in the 2016 Conservation Strategy. As stated by Kamath *et al.* (2015, p. 5517), the current effective population size is sufficiently large to avoid substantial accumulation of inbreeding depression, thereby reducing concerns regarding genetic factors affecting the viability of GYE grizzly bears. However, the Service recognizes that the long-term viability of the GYE grizzly bear population will benefit from occasional gene flow from nearby grizzly bear populations like that in the NCDE. Thus, efforts will continue to facilitate occasional movement of male bears between the NCDE and GYE (WGFD 2016, p. 13).

To increase the likelihood of occasional genetic interchange between the GYE grizzly bear population and the NCDE grizzly bear population, the State of Montana has indicated they will manage discretionary mortality in this area in order to retain the opportunity for natural movements of bears between ecosystems. Translocation of bears between these ecosystems will be a last resort and will be implemented only if there are demonstrated effects of lowered heterozygosity among GYE grizzly bears or other genetic measures that indicate a decrease in genetic diversity, as monitored by the IGBST (WGFD 2016, p. 13).

To document natural connectivity between the GYE and the NCDE, Federal and State agencies will continue to monitor bear movements on the northern periphery of the GYE grizzly bear DPS boundaries and the southern edges of the NCDE using radio-telemetry and will collect genetic samples from all captured or dead bears to document possible gene flow between these two ecosystems (YES 2016a, pp. 51–53). These genetic samples will detect migrants using an ''assignment test'' to identify the area from which individuals are most likely to have originated based on their unique genetic signature (Paetkau *et al.* 1995, p. 348; Waser and Strobeck 1998, p. 43; Paetkau *et al.* 2004, p. 56; Proctor *et al.* 2005, pp. 2410–2412). This technique also identifies bears that may be the product of reproduction between GYE and NCDE grizzly bears (Dixon *et al.* 2006, p. 158). In addition to monitoring for gene flow and movements, the signatories to the 2016 Conservation Strategy will continue interagency efforts to provide and maintain movement opportunities for grizzly bears, and reestablish natural connectivity and gene flow between the GYE grizzly bear DPS and other grizzly bear populations. To promote natural connectivity, there are attractant storage rules on public lands between the GYE and other grizzly bear Recovery Zones in the NCDE and Bitterroot to minimize the grizzly bear-human conflicts. We do not consider connectivity to the east, west, or south a relevant issue to the GYE grizzly bear population's long-term persistence because there are no extant populations in these directions to enhance the genetic diversity of the GYE population. However, we recognize the GYE grizzly bear population could be a possible source population to re-colonize the Bitterroot Ecosystem to the west.

In summary, genetic concerns are not currently a threat to the GYE grizzly bear population (Miller and Waits 2003, p. 4338; Kamath *et al.* 2015, entire). Attractant storage orders on public lands, through a reduction in conflict situations, and careful regulation of hunting in key connectivity areas provide adequate measures to promote natural connectivity and prevent reductions in genetic diversity. The IGBST will carefully monitor movements and the presence of alleles from grizzly bear populations outside the GYE grizzly bear DPS boundaries (YES 2016a, pp. 51–53). The IGBST will continue to monitor genetic diversity of the GYE grizzly bear population so that a possible reduction in genetic diversity due to the geographic isolation of the GYE grizzly bear population will be detected and responded to accordingly with translocation of outside grizzly bears into the GYE. This approach ensures that long-term genetic diversity is not a continued threat to the GYE grizzly bear DPS. Therefore, based on the best available scientific information, we conclude that genetic diversity does not constitute a threat to the GYE grizzly bear DPS now, nor is it anticipated to in the foreseeable future.

Changes in Food Resources

A comprehensive study of the GYE grizzly bear diet documented over 266 distinct plant and animal species ranging from grasses, fungi, berries, and seeds, to fish, carrion, and other meat sources (*e.g.,* young and weakened animals). Monitoring foods comprising such a diverse diet is challenging, which is why efforts have focused on four foods with relatively high energetic value and for which abundance (or use by bears) is relatively easy to measure. The IGBST currently monitors the productivity or grizzly bear use of four grizzly bear foods in the GYE: Whitebark pine seeds, army cutworm moths, ungulates, and spawning cutthroat trout. While these are some of the highest calorie food sources available to grizzly bears in the GYE (Mealey 1975, pp. 84–86; Pritchard and Robbins 1990, p. 1647; Craighead *et al.* 1995, pp. 247–252), only whitebark pine seeds are known to have an influence on grizzly bear mortality risk and reproduction. There is no known relationship between grizzly bear mortality risk or reproduction and any other individual food (Schwartz *et al.* 2010, p. 662).

Grizzly bears consume elk and bison as winter-killed carrion in the early spring, kill calves opportunistically, consume hunter-killed carcasses or gut piles, and prey upon adults weakened during the fall breeding season. Ungulate populations are threatened by brucellosis (*Brucella abortus*) and resulting management practices

resulting in bison removal, chronic wasting disease (CWD), competition with other top predators for ungulates, and decreasing winter severity. Brucellosis does not affect bison as a food source for grizzly bears, and the subsequent removal program is managed to ''maintain a wild, free-ranging population of bison'' (USDOI NPS and USDA Animal and Plant Health Inspection Service 2000, p. 22). CWD is fatal to deer and elk but has not been detected in the GYE, and, as transmission is density-dependent (Schauber and Woolf 2003, pp. 611–612), CWD would not result in local extinction of deer or elk populations. The availability of ungulate carcasses is not anticipated to be impacted by either of these diseases such that they are a threat to the GYE grizzly bear population now or in the foreseeable future. The reintroduction of gray wolves (*Canis lupus*) to the GYE in 1995 has created competition between grizzly bears and wolves for carrion; however, there has been no documentation of negative influence on the GYE grizzly bear population (Servheen and Knight 1993, p. 36). Decreasing winter severity and length as a result of climate change could reduce spring carrion availability (Wilmers and Getz 2005, p. 574; Wilmers and Post 2006, p. 405). A reduction of winter-killed ungulates may be buffered by an increase of availability of meat to adult grizzly bears during the active season as a result of grizzly bears usually prevailing in usurping wolf-killed ungulate carcasses (Ballard *et al.* 2003, p. 262). Therefore, fluctuations in the availability of ungulates are not a threat to the GYE grizzly bear population now or in foreseeable future.

A decline in the Yellowstone cutthroat trout population has resulted from a combination of factors: the introduction of nonnative lake trout (*Salvelinus naymaycush*), a parasite that causes whirling disease (*Myxobolus cerebralis*), and several years of drought conditions in the Intermountain West (Koel *et al.* 2005, p. 10). Although there has been a corresponding decrease in grizzly bear use of cutthroat trout, only a small portion of the GYE grizzly bear population uses cutthroat trout (Haroldson *et al.* 2005, p. 175), and grizzly bears that fish in spawning streams only consume, on average, between 8 and 55 trout per year (Felicetti *et al.* 2004, p. 499). Therefore, potential declines in cutthroat trout are not currently, nor are they likely to become, a threat in the foreseeable future to the GYE grizzly bear population.

Army cutworm moths aggregate on remote, high-elevation talus slopes where grizzly bears forage on them from mid- to late summer. Grizzly bears could potentially be disturbed by backcountry visitors (White *et al.* 1999, p. 150), but this has not been documented in the GYE. The situation is monitored by the IGBST and the WGFD, who will take appropriate management action as necessary. Climate change may affect army cutworm moths by changing the distribution of plants that the moths feed on or the flowering times of the plants (Woiwod 1997, pp. 152–153). However, the GYE plant communities have a wide elevational range that would allow for distributional changes (Romme and Turner 1991, p. 382), and army cutworm moths display foraging plasticity (Burton *et al.* 1980, pp. 12–13). Therefore, potential changes to army cutworm moth availability are not likely to threaten the GYE grizzly bear population in the foreseeable future.

More details on the specific ways in which changes in ungulates, cutthroat trout, and army cutworm moths could affect the GYE grizzly bear population are discussed in detail in the 2007 final rule (72 FR 14866, March 29, 2007, 14928–14933). Our analysis focuses on the potential impacts that the loss of whitebark pine could have on the GYE grizzly bear population. While we discussed notable declines in whitebark pine due to mountain pine beetle in the 2007 final rule, the data used to estimate population growth only went through 2002. The Ninth Circuit Court of Appeals questioned our conclusions about future population viability based on data gathered before the sharp decline in whitebark pine began (*Greater Yellowstone Coalition, Inc.* v. *Servheen, et al.,* 665 F.3d 1015, 1030 (9th Cir. 2011)). To assess the population's vital rates since 2002, the IGBST completed a comprehensive demographic review using data from 2002–2011 (IGBST 2012, p. 7) and extensive analyses to determine if the decline in whitebark pine is driving observed changes in grizzly bear population vital rates (IGBST 2013, entire).

The threats to whitebark pine reported in our 2007 final rule and reiterated in our 12-month finding for whitebark pine are currently being analyzed in a Species Status Assessment (76 FR 42631, July 19, 2011). Whitebark pine is currently warranted for protected status under the Act, but that action is precluded by higher priority actions. This status is primarily the result of direct mortality due to white pine blister rust and mountain pine beetles but also less obvious impacts from climate change and fire suppression. For more details on the status of whitebark pine, please see the 2013 candidate notice of review (78 FR 70104, November 22, 2013).

Whitebark pine is a masting species, which means it produces large seed crops in some years and poor crops in other years. In the GYE, a good seed crop occurs approximately every 2 to 3 years. During years of low availability of whitebark pine seeds, grizzly bear-human conflicts tend to increase as bears use lower elevations, and when those areas are within less secure habitats (Gunther *et al.* 2004, pp. 13–15; Schwartz *et al.* 2010, pp. 661–662). Approximately six more independent females and six more independent males die across the ecosystem in poor versus good whitebark pine years (IGBST 2013, p. 25, figure 5). These mortalities are primarily due to defense of life encounters and wildlife management agency removals of conflict bears (Gunther *et al.* 2004, pp. 13–14; IGBST 2009, p. 4). Additionally, litter size and the likelihood of producing a litter may decrease slightly in years following poor whitebark pine crops (Schwartz *et al.* 2006b, p. 21). Therefore, an important question was whether decline of whitebark pine would make most years similar to years with poor seed crops.

Using data from 2002 to 2011, the IGBST documented an average annual population growth rate for the GYE grizzly bear population between 0.3 and 2.2 percent (IGBST 2012, p. 34). Although the population was still increasing in this more recent time period, it was increasing at a slower rate than in the previous time period (1983–2001) and coincided with the rapid decline of whitebark pine that began in the early 2000s. Therefore, the IGBST examined the potential influence of whitebark pine decline on the change in population growth rate. Because extrinsic, density-independent factors (*e.g.,* availability of whitebark pine seeds) and intrinsic, density-dependent factors (*i.e.,* a population with high bear density) can produce similar changes in population vital rates, the IGBST conducted several analyses to clarify and tease apart these two similar effects. The results of these analyses were summarized in a report titled ''Response of Yellowstone grizzly bears to changes in food resources: a synthesis'' (hereafter referred to as ''the Food Synthesis Report'') (IGBST 2013). Regardless of whether these changes are being driven by declines in whitebark pine or are simply an indication of the population reaching high densities, the

management response would be the same: To carefully manage human-caused mortality based on scientific monitoring of the population.

For the Food Synthesis Report, the IGBST developed a comprehensive set of research questions and hypotheses to evaluate grizzly bear responses to changes in food resources. Specifically, the IGBST asked eight questions:

(1) How diverse is the diet of GYE grizzly bears?

(2) Has grizzly bear selection of whitebark pine habitat decreased as tree mortality increased?

(3) Has grizzly bear body condition decreased as whitebark pine declined?

(4) Has animal matter provided grizzly bears with an alternative food resource to declining whitebark pine?

(5) Have grizzly bear movements increased during the period of whitebark pine decline (2000–2011)?

(6) Has home range size increased as grizzly bears sought alternative foods, or has home-range size decreased as grizzly bear density increased?

(7) Has the number of human-caused grizzly bear mortalities increased as whitebark pine decreased?

(8) Are changes in vital rates during the last decade associated more with decline in whitebark pine resources than increases in grizzly bear density?

The preliminary answers to these questions are contained in the Synthesis Report and the final results have been (or will be) published in peer-reviewed journals (in their entirety: Bjornlie *et al.* 2014a; Costello *et al.* 2014; Gunther *et al.* 2014; Schwartz *et al.* 2014a and 2014b; van Manen *et al.* 2016; Ebinger *et al.* 2016; Haroldson *et al. in prep.*).

Key findings of the Synthesis Report are summarized below. To address the first question about how diverse diets of grizzly bears in the GYE are, Gunther *et al.* (2014, entire) conducted an extensive literature review and documented over 260 species of foods consumed by grizzly bears in the GYE, representing four of the five kingdoms of life (for more information, please see the proposed rule, 81 FR 13174, March 11, 2016). Regarding the second research question, if whitebark pine seeds were highly selected over other fall foods, grizzly bears would continue to seek this food even if availability declined. Costello *et al.* (2014, p. 2013) found that grizzly bear selection of whitebark pine habitat and duration of use decreased between 2000 and 2011. Additionally, (regarding the third research question) if grizzly bears were dependent on whitebark pine to meet their nutritional requirements, body condition would be expected to have decreased. Schwartz *et al.* (2014a, p. 75) and the IGBST (2013, p. 18) found body mass and percent body fat in the fall had not changed from 2000 to 2010. When they examined trends in females only, the data showed a moderate decline in female body fat during the fall, starting around 2006 (Schwartz *et al.* 2014a, p. 72). However, they suggested it could be the result of small sample sizes (n = 2.6 bears/year) and noted the data for 2011 (not included in their published paper) showed an increase in fall body fat for females, ultimately cautioning that more data were needed before it could be determined if there was truly a trend (Schwartz *et al.* 2014a, p. 76). In the Food Synthesis Report, the IGBST revisited the previous analysis with data collected since 2010, and concluded that body condition was not different between poor and good years of whitebark pine production (IGBST 2013, p. 18).

In response to the fourth research question, in years with poor whitebark pine seed production, grizzly bears shifted their diets and consumed more meat (Schwartz *et al.* 2014a, p. 68). These results were consistent with previous findings (Mattson 1997, p. 169). Given these observations of diet shifts, Ebinger *et al.* (2016, p. 705) examined whether grizzly bear use of ungulate carcasses in the fall had increased during the period of whitebark pine decline. This was indeed the case, supporting the interpretation that responses to changing food resources were primarily behavioral. In response to the fifth and sixth questions, if overall food resources were declining, one would expect daily movements, fall movements, and home range sizes to increase if bears were roaming more widely in search of foods. However, movement rates did not change during 2000 to 2011, suggesting that grizzly bears were finding alternate foods within their home range as whitebark pine seeds became less available over the past decade (Costello *et al.* 2014, p. 2013). For females, home ranges actually decreased in size from the period before (1989–1999) to the period after (2007–2012) whitebark pine decline. This decrease was greater in areas with higher grizzly bear densities but showed no relationship with the amount of live whitebark pine in the home range (Bjornlie *et al.* 2014b, pp. 4–6). Male home ranges did not change in size (Bjornlie *et al.* 2014b, pp. 4–6). Finally, at the population level, bear density, but not whitebark pine decline, was associated with lower cub survival and reproductive suppression, factors contributing to the slowing of population growth since the early 2000s. Combined, these findings suggest that changes in population vital rates since the early 2000s are more indicative of the population approaching carrying capacity than a shortage of resources (van Manen *et al.* 2016, p. 310).

In response to the seventh question, while land managers have little influence on how calories are spread across the landscape, we have much more influence on human-caused mortality risk. Consistent with findings from earlier studies, the IGBST (2013, p. 24) found that grizzly bear mortalities increased in poor compared to good whitebark pine seed production years. Assuming the poorest observed whitebark pine cone production, the IGBST (2013, p. 25) predicted an increase of 10 annual mortalities ecosystem-wide of independent females comparing 2000 with 2012, encompassing the period that coincided with whitebark pine decline (IGBST 2013, p. 25). The greatest increase in predicted mortality occurred outside the PCA, which may be partially attributable to range expansion and continued population increase (IGBST 2013, p. 25). However, increased mortality numbers during poor whitebark pine cone production years have not led to a declining population trend (IGBST 2012, p. 34), and total mortality will be maintained within the total allowable mortality limits set forth in table 3.

In response to the eighth question, the IGBST found that while whitebark pine seed production can influence reproductive rates the following year, the overall fecundity rates during the last decade (2002–2011) did not decline when compared with data from 1983–2001 (IGBST 2013, p. 32). This is important because fecundity rates are a function of both litter size and the likelihood of producing a litter, the two ways in which whitebark pine seed production may affect reproduction. Although Schwartz *et al.* (2006a, p. 21) found one-cub litters were more common in years following poor whitebark pine seed production, one-cub litters are still adequate for population growth. Furthermore, one-cub litters are still relatively uncommon following poor whitebark pine years, as evidenced by a very consistent average litter size around two since the IGBST began reporting this metric. Fecundity and mean litter size did not change between the two monitoring periods (1983–2001 versus 2002–2011) examined by the IGBST even though the availability of whitebark pine seeds declined (IGBST 2013, pp. 33–34).

In contrast to previous studies that concluded increased mortality in poor whitebark pine cone production years led to population decline in those years (Pease and Mattson 1999, p. 964), the IGBST found the population did not decline despite increased mortality in poor whitebark pine cone production years. Therefore, we determined that the conclusions of Pease and Mattson (1999, p. 964) are inaccurate. First and foremost, estimating population growth for individual, non-consecutive years, as Pease and Mattson (1999, p. 962) did, is ''not legitimate'' and results in an ''incorrect estimate'' (Eberhardt and Cherry 2000, p. 3257). Even assuming their methods of separating out individual, non-consecutive years of data for a species whose reproduction and survival are inextricably linked to multiple, consecutive years (*e.g.,* reproductive status in 1 year affects status in the following year), many other aspects of their analysis do not reflect the best available science. An important difference between Pease and Mattson (1999, p. 964) and other population growth rate estimates (Eberhardt *et al.* 1994, p. 362; Boyce 1995, entire; Schwartz *et al.* 2006b, p. 48; IGBST 2012, p. 34) is related to their treatment of conflict bears. Pease and Mattson (1999, p. 967) assumed that grizzly bears with any history of conflict would experience lower survival rates associated with conflict bears for the rest of their lives.

The findings of Schwartz *et al.* (2006b, p. 42) challenge this assumption, finding that while survival of conflict bears decreases during the year of the conflict and the next year, survival returns to approximately normal within 2 years. In other words, management-trapped bears often return to foraging on naturally occurring food sources, away from human developments. Another assumption made by Pease and Mattson (1999, p. 967) was that 73 percent of the GYE grizzly bear population were conflict bears, with correspondingly lower survival rates. However, Schwartz *et al.* (2006b, p. 39) found only about 28 percent of the GYE grizzly bear population were ever involved in conflicts. Together, these two erroneous assumptions by Pease and Mattson (1999, p. 967) resulted in a gross underestimation of population trend. As a result, we do not consider Pease and Mattson (1999) to be the best available science.

Earlier studies suggested that increased grizzly bear mortalities in poor whitebark pine cone production years are a result of bears roaming more widely in search of foods and exposing themselves to higher mortality risk in roaded habitats at lower elevations. However, Costello *et al.* (2014, p. 2014) showed that grizzly bears did not roam over larger areas or canvass more area within their fall ranges as whitebark pine declined rapidly starting in the early 2000s, and suggested bears found alternative foods within their fall ranges. Furthermore, Bjornlie *et al.* (2014b, p. 4) found that home range size has not increased after whitebark pine declined, and Schwartz *et al.* (2010, p. 662) found that when bears use lower elevations in poor whitebark pine seed production years, it is the amount of secure habitat that determines mortality risk. Meaning, in both good and poor whitebark pine seed years, survival is determined primarily by levels of secure habitat. Therefore, our approach of maintaining these levels of secure habitat on Federal lands, which comprise 98 percent of lands within the PCA and 60 percent of suitable habitat outside the PCA, provides strong mitigation against any impacts the decline of whitebark pine may have on this grizzly bear population because the mechanism driving the increased mortality risk is secure habitat, not the presence or absence of whitebark pine.

Evidence suggests that observed changes in population vital rates were driven by density-dependent effects and have resulted in a relatively flat population trajectory (van Manen 2016a, *in litt.*). Van Manen *et al.* (2016, entire) found cub survival, yearling survival, and reproductive transition (see *Glossary: Transition probability*) from no young to cubs all changed from 1983 to 2012, with lower rates evident during the last 10 years of that time period. Cub survival and reproductive transition were negatively associated with an index of grizzly bear density, indicating greater declines of those parameters where bear densities were higher. Their analysis did not support a similar relationship with estimates of decline in whitebark pine tree cover. Moreover, changes in vital rates started in the late 1990s and early 2000s (van Manen *et al.* 2016, pp. 307–308), which preceded the beginning and peak time period of whitebark pine decline. The results of van Manen *et al.* (2016, entire) support the interpretation that slowing of population growth during the last decade was associated more with increasing grizzly bear density than the decline in whitebark pine.

We recognize that changes in food resources can also influence population vital rates. These research questions and results do not refute that possibility, but the preponderance of evidence supports the conclusion that bears so far are finding alternative food resources and that those resources are sufficient to maintain body mass and body condition (IGBST 2013, p. 20; Costello *et al.* 2014, p. 2013; Schwartz *et al.* 2014a, p. 75; Ebinger *et al.* 2016, p. 705). In other words, evidence for density dependence suggests that the population may be approaching carrying capacity (van Manen *et al.* 2016, entire). The combined evidence from these recent studies further supports the recovered status of the GYE grizzly bear population. This status has remained unchanged over the last 15 years despite significant changes in food resources in the GYE.

While there was some concern that the rapid loss of whitebark pine could result in mortality rates similar to those experienced after the open-pit garbage dumps were closed in the early 1970s (Schwartz *et al.* 2006b, p. 42), we now know this has not been the case. This is most likely due to the fact that whitebark pine has never been a spatially or temporally predictable food source on the landscape like the open-pit garbage dumps were. The dumps were open year round and provided high-calorie foods the entire time. They were in the exact same location every year and for the entire season. Grizzly bears congregated at these known locations in large numbers and in very close proximity to each other and to people. None of these circumstances are true for grizzly bears foraging on whitebark pine seeds.

GYE grizzly bears have high diet diversity (Gunther *et al.* 2014, p. 65) and use alternate foods in years of low whitebark pine seed production (Schwartz *et al.* 2014a, pp. 75–76). Nearly one third of grizzly bears in the GYE do not have whitebark pine in their home range, so they do not use this food (Costello *et al.* 2014, p. 2013). Grizzly bears in the GYE that do use whitebark pine are accustomed to successfully finding alternative natural foods in years when whitebark pine seeds are not available, and body mass and body fat are not different between good and poor whitebark pine seed years (Schwartz *et al.* 2014a, pp. 72–73, 75).

The IGBST will continue to monitor annual production of common foods, grizzly bear-human conflicts, survival rates, reproductive rates, and the causes and locations of grizzly bear mortality, as detailed in the 2016 Conservation Strategy (YES 2016a, pp. 33–91). These data provide the 2016 Conservation Strategy's signatory agencies with the scientific information necessary to inform and implement adaptive management (Holling 1978, pp. 11–16) actions in response to ecological

changes that may impact the future of the GYE grizzly bear population. These management responses may involve increased habitat protection, increased mortality management, or a status review and emergency re-listing of the population if management actions are unable to address the problems.

Grizzly bears are resourceful omnivores that will make behavioral adaptations regarding food acquisition (Schwartz *et al.* 2014a, p. 75). Diets of grizzly bears vary among individuals, seasons, years, and where they reside within the GYE (Mealey 1980, pp. 284–287; Mattson *et al.* 1991*a,* pp. 1625–1626; Felicetti *et al.* 2003, p. 767; Felicetti *et al.* 2004, p. 499; Koel *et al.* 2005, p. 14; Costello *et al.* 2014, p. 2013; Gunther *et al.* 2014, pp. 66–67), reflecting their ability to find adequate food resources across a diverse and changing landscape. In other nearby areas such as the NCDE (100 miles north of the GYE), whitebark pine has been functionally extinct as a bear food for at least 40 years (Kendall and Keane 2001, pp. 228–232), yet the NCDE grizzly bear population has continued to increase and thrive with an estimated 765 bears in 2004, and a subsequent average 3 percent annual rate of growth (Kendall *et al.* 2009, p. 9; Mace *et al.* 2012, p. 124). Similarly, although whitebark pine seed production and availability of cutthroat trout in the Yellowstone Lake area varied dramatically over the last 3 decades due to both natural and human-introduced causes (Reinhart and Mattson 1990, pp. 345–349; Podruzny *et al.* 1999, pp. 134–137; Felicetti *et al.* 2004, p. 499; Haroldson *et al.* 2005, pp. 175–178; Haroldson 2015, p. 47; Teisberg *et al.* 2014a, pp. 375–376), the GYE grizzly bear population has continued to increase and expand during this time period despite these changes in foods (Schwartz *et al.* 2006a, p. 66; IGBST 2012, p. 34; Bjornlie *et al.* 2014a, p. 184).

The GYE grizzly bear population has been coping with the unpredictable nature of whitebark pine seed production for millennia. Grizzly bears are not dependent upon whitebark pine seeds for survival, nor do they have a diet that is specialized on consumption of these seeds. While we know whitebark pine seed production can influence reproductive and survival rates, it has not caused a negative population trend, as evidenced by a relatively constant population size between 2002 and 2014 (IGBST 2012, p. 34; van Manen 2016a, *in litt.*). As articulated in the Food Synthesis Report by the IGBST (IGBST 2013, pp. 32–35) and supporting studies (in their entirety: Bjornlie *et al.* 2014b; Costello *et al.* 2014; Gunther *et al.* 2014), the demonstrated resiliency to declines in whitebark pine seed production and other high-calorie foods such as cutthroat trout shows that changes in food resources are not likely to become substantial impediments to the long-term persistence of the GYE grizzly bear population.

In *Greater Yellowstone Coalition* v. *Servheen,* 665 F.3d 1015 (9th Cir. 2011), the Ninth Circuit faulted the Service's conclusion that whitebark pine losses did not pose a threat to grizzly bears. First, the Ninth Circuit noted that grizzly bears' adaptability and resourcefulness increased the threat from whitebark pine loss because it raised the risk of conflicts with humans as bears looked for other food sources. The Service acknowledges this component of the threat from whitebark pine loss, but despite increased mortality during poor whitebark pine cone production years, the population trend has maintained a relatively flat trajectory (IGBST 2012, p. 34; van Manen 2016a; *in litt.*). Additionally, during years of poor whitebark pine seed availability, grizzly bears did not roam over larger areas (Costello *et al.* 2014, p. 2014); rather, the increased risk of mortality was related to the use of lower elevations and less secure habitat within their home range (Schwartz *et al.* 2010, p. 662).

Second, the court noted that the Service's data on long-term population growth came from 2002, before the pine beetle epidemic began. The population growth rate slowed from the 4 to 7 percent that occurred from 1983 to 2001 (Eberhardt *et al.* 1994, p. 362; Knight and Blanchard 1995, pp. 18–19; Schwartz *et al.* 2006b, p. 48), to 0.3 to 2.2 percent from 2002 to 2011 (IGBST 2012, p. 34). The population trajectory that includes the most recent data indicates no statistical trend (*i.e.,* relatively flat population trajectory) within the DMA for the period 2002 to 2014 (van Manen 2016a, *in litt.*). Third, the court faulted the Service for using a study of NCDE bears to prove GYE grizzly bears continued to increase despite whitebark pine losses, even though GYE bears were reported to be unique because of their reliance on whitebark pine seeds. Current data show that the GYE bear population has stabilized or increased despite the loss of whitebark pine seeds (IGBST 2012, p. 34; van Manen 2016b, *in litt.*). A recent study found that nearly one third of collared grizzly bears in the GYE did not even have whitebark pine within their home ranges and those that did made use of other foods within their home ranges during poor whitebark pine years (Costello *et al.* 2014, pp. 2009, 2013).

Fourth, the Ninth Circuit observed that the Service contradicted itself by stating that the entire PCA was necessary to support a recovered population, yet acknowledged that whitebark pine would persist in only a small part of the PCA. New data show that, despite the decline in whitebark pine, the GYE population has been relatively constant, is close to carrying capacity, and is exhibiting density-dependent regulation inside the DMA (van Manen *et al.* 2016, entire; van Manen 2016b, *in litt.*). Fifth, the court determined it was arbitrary and capricious for the Service to rely on scientific uncertainty about whitebark pine loss in a delisting decision. Any uncertainty about the loss of whitebark pine has been resolved by GYE population numbers that show a relatively stable population size despite loss of whitebark pine seeds (IGBST 2012, p. 34; van Manen 2016b, *in litt.*) and no long-term changes in vital rates (IGBST 2012, pp. 32–34). Furthermore, whitebark pine tree mortality has significantly slowed since 2009, suggesting that the current beetle outbreak may have run its course (Haroldson 2015, p. 47). Finally, the Ninth Circuit faulted the Service for relying on adaptive management and monitoring without describing management responses and specific triggering criteria. The population objectives that will be incorporated into regulations provide specific triggers for management action (see *Factors B and C Combined* discussion, above). The Service continues to believe that adaptive management will play a role in future management decisions because new data and new information will require appropriate management responses.

In summary, the best scientific and commercial data available regarding grizzly bear responses to food losses suggest this issue is not a threat to the GYE grizzly bear population and is not an impediment to long-term population persistence. Therefore, we conclude that changes in food resources do not constitute a threat to the GYE grizzly bear DPS now, nor are such changes anticipated to constitute a threat in the foreseeable future.

Climate Change

Our analyses under the Act include consideration of observed or likely environmental changes resulting from ongoing and projected changes in climate. As defined by the Intergovernmental Panel on Climate Change (IPCC), the term ''climate'' refers

to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2013a, p. 1450). The term ''climate change'' thus refers to a change in the state of the climate that can be identified by changes in the mean or the variability of relevant properties, which persists for an extended period, typically decades or longer, due to natural conditions (*e.g.,* solar cycles), or human-caused changes in the composition of the atmosphere or in land use (IPCC 2013a, p. 1450).

Scientific measurements spanning several decades demonstrate that changes in climate are occurring. In particular, warming of the climate system is unequivocal, and many of the observed changes in the last 60 years are unprecedented over decades to millennia (IPCC 2013b, p. 4). The current rate of climate change may be as fast as any extended warming period over the past 65 million years and is projected to accelerate in the next 30 to 80 years (National Research Council 2013, p. 5). Thus, rapid climate change is adding to other sources of extinction pressures, such as land use and human-caused mortality, which will likely place extinction rates in this era among just a handful of the severe biodiversity crises observed in Earth's geological record (American Association for the Advancement of Sciences 2014, p. 17).

Examples of various other observed and projected changes in climate and associated effects and risks, and the bases for them, are provided for global and regional scales in recent reports issued by the IPCC (in their entirety: 2013b, 2014), and similar types of information for the United States and regions within it are available via the National Climate Assessment (Melillo *et al.* 2014, entire). Results of scientific analyses presented by the IPCC show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate and is ''extremely likely'' (defined by the IPCC as 95–100 percent likelihood) to be due to the observed increase in greenhouse gas concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from fossil fuel use (IPCC 2013b, p. 17).

Scientists use a variety of climate models, which include consideration of natural processes and variability, as well as various scenarios of potential levels and timing of greenhouse gas emissions, to evaluate the causes of changes already observed and to project future changes in temperature and other climate conditions. Model results yield very similar projections of average global warming until about 2030, and thereafter the magnitude and rate of warming vary through the end of the century depending on the assumptions about population levels, emissions of greenhouse gases, and other factors that influence climate change. Thus, absent extremely rapid stabilization of greenhouse gas emissions at a global level, there is strong scientific support for projections that warming will continue through the 21st century, and that the magnitude and rate of change will be influenced substantially by human actions regarding greenhouse gas emissions (IPCC 2013b, p. 19; IPCC 2014, entire).

Global climate projections are informative, and, in some cases, the only or the best scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (in their entirety: IPCC 2013b, 2014), and within the U.S. (Melillo *et al.* 2014, entire). Therefore, we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling).

The hydrologic regime in the Rocky Mountains has changed and is projected to change further (Bartlein *et al.* 1997, p. 786; Cayan *et al.* 2001, p. 411; Leung *et al.* 2004, p. 75; Stewart *et al.* 2004, pp. 223–224; Pederson *et al.* 2011, p. 1666). The western United States may experience milder, wetter winters with warmer, drier summers and an overall decrease in snowpack (Leung *et al.* 2004, pp. 93–94). While some climate models do not demonstrate significant changes in total annual precipitation for the western United States (Duffy *et al.* 2006, p. 893), an increase in ''rain on snow'' events is expected (Leung *et al.* 2004, p. 93; McWethy *et al.* 2010, p. 55). The amount of snowpack and the timing of snowmelt may also change, with an earlier peak stream flow each spring (Cayan *et al.* 2001, p. 410; Leung *et al.* 2004, p. 75; Stewart *et al.* 2004, pp. 223–224). Although there is some disagreement about changes in the water content of snow under varying climate scenarios (Duffy *et al.* 2006, p. 893), reduced runoff from decreased snowpack could translate into decreased soil moisture in the summer (Leung *et al.* 2004, p. 75). However, Pederson *et al.* (2011, p. 1682) found that increased spring precipitation in the northern Rocky Mountains is offsetting these impacts to total annual stream flow from expected declines in snowpack thus far.

The effects related to climate change may result in a number of changes to grizzly bear habitat, including a reduction in snowpack levels, shifts in denning times, shifts in the abundance and distribution of some natural food sources, and changes in fire regimes. Most grizzly bear biologists in the United States and Canada do not expect habitat changes predicted under climate change scenarios to directly threaten grizzly bears (Servheen and Cross 2010, p. 4). These changes may even make habitat more suitable and food sources more abundant (Servheen and Cross 2010, Appendix D). However, these ecological changes may affect the timing and frequency of grizzly bear-human interactions and conflicts (Servheen and Cross 2010, p. 4).

Because timing of den entry and emergence is at least partially influenced by food availability and weather (Craighead and Craighead 1972, pp. 33–34; Van Daele *et al.* 1990, p. 264), less snowpack would likely shorten the denning season as foods become available later in the fall and earlier in the spring. In the GYE, Haroldson *et al.* (2002, pp. 34–35) reported later den entry dates for male grizzly bears, corresponding with increasing November temperatures from 1975 to 1999. This increased time outside of the den could increase the potential for conflicts with humans (Servheen and Cross 2010, p. 4).

The effects related to climate change could create temporal and spatial shifts in grizzly bear food sources (Rodriguez *et al.* 2007, pp. 41–42). Changes in plant communities have already been documented, with species' ranges shifting farther north and higher in elevation due to environmental constraints (Walther *et al.* 2002, pp. 390–391; Walther 2003, pp. 172–175; Walther *et al.* 2005, p. 1428) and increases in outbreaks of insects that reduce survival (Bentz *et al.* 2010, entire). It is unclear whether avalanche chutes, an important habitat component to grizzly bears, will decrease, possibly as a result of decreased snowpack, or increase, as a result of increases in ''rain on snow'' events that may decrease the stability of snowpack. Changes in vegetative food distributions also may influence other mammal distributions, including potential prey species like ungulates. While the extent and rate to which individual plant species will be impacted is difficult to foresee with any level of confidence (in their entirety: Walther *et al.* 2002; Fagre *et al.* 2003),

there is general consensus that grizzly bears are flexible enough in their dietary needs that they will not be impacted directly by ecological constraints such as shifts in food distributions and abundance (Servheen and Cross 2010, p. 4; IGBST 2013, p. 35).

Fire regimes can affect the abundance and distribution of some vegetative bear foods (*e.g.,* grasses, berry-producing shrubs) (LeFranc *et al.* 1987, p. 150). For instance, fires can reduce canopy cover, which usually increases berry production. However, on steep south or west slopes, excessive canopy removal due to fires or vegetation management may decrease berry production through subsequent moisture stress and exposure to sun, wind, and frost (Simonin 2000, entire). Fire frequency and severity may increase with late summer droughts predicted under climate change scenarios (Nitschke and Innes 2008, p. 853; McWethy *et al.* 2010, p. 55). Increased fire frequency has the potential to improve grizzly bear habitat, with low to moderate severity fires being the best. For example, fire treatment most beneficial to huckleberry shrubs is that which results in damage to stems, but does little damage to rhizomes (Simonin 2000, entire). High-intensity fires may reduce grizzly bear habitat quality immediately afterwards by decreasing hiding cover and delaying regrowth of vegetation, although Blanchard and Knight (1996, p. 121) found that increased production of forbs and root crops in the years following the high-intensity, widespread Yellowstone fires of 1988 benefited grizzly bears. Because grizzly bears have shown resiliency to changes in vegetation resulting from fires, we do not anticipate altered fire regimes predicted under most climate change scenarios will have significant negative impacts on grizzly bear survival or reproduction, despite the potential effects on vegetation. Therefore, we conclude that the effects of climate change do not constitute a threat to the GYE grizzly bear DPS now, nor are they anticipated to in the foreseeable future.

Catastrophic Events

Here we analyze a number of possible catastrophic events including fire, volcanic activity, and earthquake. Fire is a natural part of the GYE system; however, 20th century forest management, which included extensive wildfire suppression efforts, promoted heightened potential for a large fire event. The 1988 fires, the largest wildfires in YNP's recorded history, burned a total of 3,213 km^2 (1,240 mi^2) or 36 percent of the Park. However, large mobile species such as grizzly bears and their ungulate prey usually were not meaningfully adversely affected. Surveys after the 1988 fires found that 345 elk, 36 deer, 12 moose, 6 black bears, and 9 bison died in GYE as a direct result of the conflagration (YNP 2011, p. 3). Regarding impacts to grizzly bears, YNP concluded, ''Grizzly bears have evolved in association with landscapes strongly influenced by fire, the primary forest disturbance agent within the GYE, are highly vagile, and are adaptable to changing ecological conditions. Wildland fires will provide significant long-term benefits to grizzly bears by maintaining natural ecosystem processes'' (YNP 2005, Appendix H). YNP's fire management policy (YNP 2014a, entire) indicates natural wildfires should be allowed to burn, so long as parameters regarding fire size, weather, and potential danger are not exceeded. Those fires that do exceed the standards set forth in the fire management policy, as well as all human-caused fires, are to be suppressed (YNP 2014a, entire). National Forests manage natural wildfires to allow them to play their ''natural ecological role'' while ''minimizing negative effects to life, investments and valuable resources'' (Caribou-Targhee NF 2005, p. 11; USDA FS 2011, pp. 3–4; Shoshone NF 2012, p. 2; Bridger-Teton NF 2015, p. 8). Future fires are likely in the GYE system. Overall, we agree with the YNP conclusion (YNP 2005, Appendix H) that grizzly bears are adaptable and will benefit from fires in the long term. Wildfires often lead to an increase in ungulate food supplies and an increase in ungulate numbers. While minor, localized, short-term impacts are likely, fire will not threaten the viability of the grizzly bear population in the GYE.

The GYE has also experienced several exceedingly large volcanic eruptions in the past 2.1 million years. Super eruptions occurred 2.1 million, 1.3 million, and 640,000 years ago (Lowenstern *et al.* 2005, pp. 1–2). Such a similar event would devastate the GYE. While one could argue ''we are due'' for such an event, scientists with the Yellowstone Volcano Observatory maintain that they ''see no evidence that another cataclysmic eruption will occur at Yellowstone in the foreseeable future. . . [and that] recurrence intervals of these events are neither regular nor predictable'' (Lowenstern *et al.* 2005, p. 6). We agree and do conclude that such an event is not likely within the foreseeable future.

More likely to occur is a nonexplosive lava flow eruption or a hydrothermal explosion. There have been 30 nonexplosive lava flows in YNP over the last 640,000 years, most recently 70,000 years ago (Lowenstern *et al.* 2005, p. 2). During such an eruption, flows ooze slowly over the surface, moving a few hundred feet per day for several months or several years (Lowenstern *et al.* 2005, p. 2). Any renewed volcanic activity at YNP would most likely take this form (Lowenstern *et al.* 2005, p. 3). In general, such events would have localized impacts and be far less devastating than a large eruption (although such an event could also cause fires; fire as a threat is discussed above). Hydrothermal explosions, triggered by sudden changes in pressure of the hydrothermal system, also occasionally affect the region. More than a dozen large hydrothermal explosion craters formed between 14,000 and 3,000 years ago (Lowenstern *et al.* 2005, p. 4). The largest hydrothermal-explosion crater documented in the world is along the north edge of Yellowstone Lake in an embayment known as Mary Bay; this 2.6-km (1.5-mi) diameter crater formed about 13,800 years ago (Lowenstein *et al.* 2005, p. 4). We do not consider either nonexplosive lava flow eruptions or a hydrothermal-explosion likely within the foreseeable future, but even if one of these did occur, the impact to grizzly bears would likely be localized, temporary, and would not threaten the viability of the grizzly bear population in the GYE.

Earthquakes also occur in the region. The most notable earthquake in YNP's recent history was a magnitude 7.5 in 1959 (Lowenstern *et al.* 2005, p. 3). Similarly, a magnitude 6.5 earthquake hit within YNP in 1975 (Lowenstern *et al.* 2005, p. 3). The 1959 earthquake killed 28 people, most of them in a massive landslide triggered by the quake (Lowenstern *et al.* 2005, p. 3). Such massive landslides and other earthquake-related impacts could also affect wildlife. But as with other potential catastrophic events, the impact of a large earthquake to grizzly bears would be localized, temporary, and would not threaten the viability of the grizzly bear in the GYE.

We considered catastrophic and stochastic (random probability) events that might reasonably occur in the GYE within the foreseeable future, to the extent possible. Most catastrophic events discussed above are unpredictable and unlikely to occur within the foreseeable future. Other events that might occur within the foreseeable future would likely cause only localized and temporary impacts that would not threaten the GYE grizzly bear population.

Public Support and Human Attitudes

Public support is paramount to any successful large carnivore conservation program (Servheen 1998, p. 67). Historically, human attitudes played a primary role in grizzly bear population declines by promoting a culture and government framework that encouraged excessive, unregulated, human-caused mortality. Through government-endorsed eradication programs and perceived threats to human life and economic livelihood, humans settling the Western United States were able to effectively eliminate most known grizzly bear populations after only 100 years of westward expansion.

We have seen a change in public perceptions and attitudes toward the grizzly bear in the last several decades. The same government that once financially supported active extermination of the bear now uses its resources to protect the great symbol of American wildness. This change in government policy and practice is a product of changing public attitudes about the grizzly bear. Although attitudes about grizzly bears vary geographically and demographically, there has been a revival of positive attitudes toward the grizzly bear and its conservation (Kellert *et al.* 1996, pp. 983–986).

Public outreach presents a unique opportunity to effectively integrate human and ecological concerns into comprehensive programs that can modify societal beliefs about, perceptions of, and behaviors toward grizzly bears. Attitudes toward wildlife are shaped by numerous factors including basic wildlife values, biological and ecological understanding of species, perceptions about individual species, and specific interactions or experiences with species (Kellert 1994, pp. 44–48; Kellert *et al.* 1996, pp. 983–986). I&E programs teach visitors and residents about grizzly bear biology, ecology, and behavior, and enhance appreciation for this large predator while dispelling myths about its temperament and feeding habits. Effective I&E programs have been an essential factor contributing to the recovery of the GYE grizzly bear population since its listing in 1975. By identifying values common to certain user groups, the I&E working group can disseminate appropriate materials and provide workshops catered to these values. By providing general information to visitors and targeting specific user groups about living and working in grizzly bear country, we believe continued coexistence between grizzly bears and humans will be accomplished.

Traditionally, residents of the GYE involved in resource extraction industries, such as loggers, miners, livestock operators, and hunting guides, were opposed to land-use restrictions that were perceived to place the needs of the grizzly bear above human needs (Kellert 1994, p. 48; Kellert *et al.* 1996, p. 984). Surveys of these user groups have shown that they tolerate large predators when they are not seen as direct threats to their economic stability or personal freedoms (Kellert *et al.* 1996, p. 985). Delisting could increase acceptance of grizzly bears by giving local government and private citizens more discretion in decisions that affect them. Increased flexibility regarding livestock depredating bears in areas outside of the PCA may increase tolerance for the grizzly bear by landowners and livestock operators by potentially reducing the number of conflict situations.

Ultimately, the future of the grizzly bear will depend on the people who live, work, and recreate in grizzly bear habitat and the willingness and ability of these people to learn to coexist with the grizzly bear and to accept this animal as a cohabitant of the land. Other management strategies are unlikely to succeed without effective and innovative public I&E programs. The objective of the I&E is to proactively address grizzly bear-human conflicts by informing the public about the root causes of these conflicts and providing suggestions on how to prevent them (YES 2016a, pp. 92–95). By increasing awareness of grizzly bear behavior and biology, we hope to enhance public involvement and appreciation of the grizzly bear. In addition to public outreach programs, the States have implemented other programs to help reduce conflicts with the people that are directly affected by grizzly bears. These efforts include livestock carcass removal programs, electric fencing subsidies for apiaries and orchards, and sharing costs of bear-resistant garbage bins where appropriate.

Although some human-caused grizzly bear mortalities are unintentional (*e.g.,* vehicle collisions, trap mortality), intentional deaths in response to grizzly bear-human conflicts are responsible for the majority of known and probable human-caused mortalities. Fortunately, this source of mortality can be reduced significantly if adequate I&E are provided to people who live, work, and recreate in occupied grizzly bear habitat and proper management infrastructure is in place (Linnell *et al.* 2001, p. 345). For example, even though more than 3 million people visit the National Parks and National Forests of the GYE each year, (USDA FS 2006a, pp. 176, 183, 184; Cain 2014, p. 46; Gunther 2014, p. 47), the average number of conflicts per year between 1992 and 2010 was only 150 (Gunther *et al.* 2012, p. 51). The current I&E working group has been a major component contributing to the successful recovery of the GYE grizzly bear population over the last 30 years. Both Federal and State management agencies are committed to continuing to work with citizens, landowners, and visitors within the GYE grizzly bear DPS boundaries to address the human sources of conflicts.

From 1980 through 2002, at least 36 percent (72 out of 196) of human-caused mortalities may have been avoided if relevant I&E materials had been presented, understood, and used by involved parties (Servheen *et al.* 2004, p. 15). Educating back- and front-country users about the importance of securing potential bear attractants can reduce grizzly bear mortality risk. Similarly, adhering to hiking recommendations, such as making noise, hiking with other people, and hiking during daylight hours, can further reduce grizzly bear mortalities by decreasing the likelihood that hikers will encounter bears. Hunter-related mortalities may involve hunters defending their life because of carcasses that are left unattended or stored improperly. Grizzly bear mortalities also occur when hunters mistake grizzly bears for black bears. All of these circumstances can be further reduced through I&E programs.

Outside the PCA, State wildlife agencies recognize that the key to preventing grizzly bear-human conflicts is providing I&E to the public. State grizzly bear management plans also acknowledge that this is the most effective long-term solution to grizzly bear-human conflicts and that adequate public outreach programs are paramount to ongoing grizzly bear survival and successful coexistence with humans in the GYE so that the measures of the Act continue not to be necessary. All three States have been actively involved in I&E outreach for over a decade, and their respective management plans contain chapters detailing efforts to continue current programs and expand them when possible. For example, the WGFD created a formal grizzly bear-human conflict management program in July 1990 and has coordinated an extensive I&E program since then. Similarly, since 1993, MFWP has implemented countless public outreach efforts to minimize bear-human conflicts, and the

IDFG has organized and implemented education programs and workshops focused on private and public lands on the western periphery of the grizzly bear's range.

Compensating ranchers for losses caused by grizzly bears is another approach to build support for coexistence between livestock operators and grizzly bears. In cases of grizzly bear livestock depredation that have been verified by USDA Animal and Plant Health Inspection Service's Wildlife Services, IDFG, MFWP, or WGFD, affected livestock owners are compensated. Since 1997, compensation in Montana and Idaho has been provided primarily by private organizations, principally Defenders of Wildlife. Since the program's inception in 1997, the Defenders of Wildlife Grizzly Bear Compensation Trust paid over $400,000 to livestock operators in the northern Rockies for confirmed and probable livestock losses to grizzly bears (Edge 2013, entire). In 2013, the State of Montana passed legislation establishing a compensation program for direct livestock losses caused by grizzly bears (MCA 2–15–3113). In light of this legislation, Defenders of Wildlife stopped their compensation program in Montana and redirected funds to other conflict prevention programs.

In Wyoming, compensation has always been paid directly by the State. Upon delisting, both Idaho and Wyoming's grizzly bear management plans call for State funding of compensation programs (Idaho's Grizzly Bear Delisting Advisory Team 2002, p. 16; WGFD 2016, pp. 53–55). In Idaho, compensation funds would come from the secondary depredation account, and the program would be administered by the appropriate IDFG Regional Landowner Sportsman Coordinators and Regional Supervisors (Idaho's Grizzly Bear Delisting Advisory Team 2002, p. 16). In Wyoming, the WGFD will pay for all compensable damage to agricultural products as provided by State law and regulation (WGFD 2016, p. 58). The WGFD will continue efforts to establish a long-term funding mechanism to compensate property owners for livestock and apiary losses caused by grizzly bears. In Montana, long-term funding to compensate livestock owners for direct kills has been secured through the general fund. A long-term funding source has not been identified for conflict prevention projects but is being actively pursued. Based on the analysis provided above, we conclude that, through the positive influence of the I&E program, public support and attitude does not constitute a threat to the GYE grizzly bear DPS now, nor is it anticipated to in the foreseeable future.

Summary of Factor E

Factor E requires the Service to consider other natural or man-made factors affecting a species' continued existence. The following factors warranted consideration as possible threats to the GYE grizzly bear population: Effects due to: (1) Genetic health, (2) potential changes in food resources, (3) climate change, (4) catastrophic events, and (5) human attitudes toward grizzly bear recovery. We do not consider genetic concerns to be a threat for the following reasons: We have an effective population size more than four times that recommended by the best available science; we know levels of genetic diversity have not declined in the last century; we know current levels of genetic diversity are sufficient to support healthy reproduction and survival; and we know that genetic contribution from individual bears outside of the GYE will not be necessary for the next several decades (Miller and Waits 2003, p. 4338; Kamath *et al.* 2015, entire). We do not anticipate that genetic issues will affect grizzly bears in the future because of ongoing efforts to restore natural connectivity and a commitment to translocate animals in the future, if needed, as provided in the 2016 Conservation Strategy.

Because the GYE grizzly bear population has increased or remained relatively constant in size during declines in whitebark pine seed production and other high-calorie foods since the early 1990s, there is no evidence that changes in food resources will become substantial impediments to the long-term persistence of the GYE grizzly bear population. Changing climate conditions have the potential to affect grizzly bear habitat with subsequent implications for grizzly bear-human conflicts. While we do not consider the effects of climate change to be a direct threat to grizzly bear habitat in the GYE, it could influence the timing and frequency of some grizzly bear-human conflicts with possible increases in grizzly bear mortality. This possible increase in grizzly bear mortality risk is not expected to be a threat because of coordinated total mortality limits within the DMA (see table 3 and *Factors B and C Combined* discussion, above). Catastrophic fires, volcanic eruptions, and earthquakes are unlikely to occur in the foreseeable future or would likely cause only localized and temporary impacts to the GYE grizzly bear population. Finally, we do not anticipate human attitudes becoming a threat to the GYE grizzly bear population due to effective outreach programs and established regulatory frameworks.

Essentially, the management response to all of these potential threats would be to limit human-caused mortality through conflict prevention and management to limit discretionary mortality (see table 3 and *Factors B and C Combined* discussion, above). Because of the manageable nature of these potential threats through conflict prevention and response efforts and the large area of suitable, secure habitat within the GYE, we do not consider them to be a threat to the GYE grizzly bear DPS now or in the foreseeable future.

Cumulative Effects of Factors A Through E

Many of the threats faced by grizzly bears are interrelated and could be synergistic. Principal threats discussed above include habitat loss through road building and the resulting increased human access to grizzly bear habitat, human-caused mortality of grizzly bears, and the legal mechanisms that direct habitat and population management. The principal threats assessed in previous sections may cumulatively impact the GYE grizzly bear population beyond the scope of each individual threat. For example, the loss of whitebark pine could lead to lower survival rates at the same time of the year when grizzly bears are vulnerable to human-caused mortality from elk hunting. Alternatively, expected increases in human populations across the Western United States and climate change both have the potential to increase grizzly bear conflicts and human-caused mortality. Historically, each of these factors impacted grizzly bears in the GYE and cumulatively acted to reduce their range and abundance over time. Today, these stressors have been adequately minimized and ameliorated and do not impact the GYE grizzly bear population with the same intensity.

While these numerous stressors on grizzly bear persistence are challenging to conservation, our experience demonstrates that it is possible for large carnivore conservation to be compatible with them (Linnell *et al.* 2001, p. 48). Despite these risks, the best available data indicate the GYE grizzly bear population's trend has been relatively constant with no evidence to date of a decline, and range extent has continued to expand. We consider estimates of population trend (*i.e.,* ''lambda'') to be the ultimate metric to assess cumulative impacts to the population. It reflects all

of the various stressors on the population. This calculation reflects total mortality, changes in habitat quality, changes in population density, change in current range, displacement effects, and so forth. In other words, there will always be stressors acting on the GYE grizzly bear population that lead to human-caused mortality or displacement, but if these are not causing the population to decline, we cannot consider them substantial.

Summary of Factors Affecting the Greater Yellowstone Ecosystem Grizzly Bear Population

The primary factors related to past habitat destruction and modification have been reduced through changes in management practices that have been formally incorporated into regulatory documents. Maintenance of the 1998 baseline values for secure habitat, developed sites on public lands, and livestock allotments inside the PCA will adequately ameliorate the multitude of stressors on grizzly bear habitat such that they do not become threats to the GYE grizzly bear population in the foreseeable future. We expect many of the threats discussed under *Factor A* to continue to occur at some level, but they are sufficiently ameliorated so they affect only a small proportion of the population.

Upon delisting, the GYE National Forests and National Parks will continue to implement and maintain the 1998 baseline. Together, these two Federal agencies manage 98 percent of lands within the PCA and 88 percent of all suitable habitat within the DPS boundaries. Suitable habitat outside the PCA provides additional ecological resiliency and habitat redundancy to allow the population to respond to environmental changes. Habitat protections specifically for grizzly bear conservation are not necessary here because other regulatory mechanisms that limit development and motorized use are already in place for nearly 60 percent of suitable habitat outside the PCA. These and other conservation measures discussed in the USFS's Record of Decision (2006b) ensure threats to the GYE grizzly bear population's habitat outside the PCA will not become substantial enough to threaten this population's long-term persistence. Therefore, based on the best available information and expectation that current management practices will continue into the foreseeable future, we conclude that the present or threatened destruction, modification, or curtailment of its habitat or range does not constitute a threat to the GYE grizzly bear DPS and is not expected to become a threat in the foreseeable future.

When grizzly bears were listed in 1975, we identified human-caused mortality, mainly ''indiscriminate illegal killing'' and management removals, as threats to the population under *Factors B and C Combined.* In response, we implemented demographic recovery criteria to maintain a minimum population size and a well-distributed population and to establish total mortality limits based on scientific data and direct monitoring of the population. Since implementing these criteria, the GYE grizzly bear population has tripled in size and range (Eberhardt *et al.* 1994, pp. 361–362; Knight and Blanchard 1995, pp. 2–11; Boyce *et al.* 2001, pp. 1–11; Schwartz *et al.* 2006b, p. 48; Pyare *et al.* 2004, pp. 5–6; Schwartz *et al.* 2006a, pp. 64–66; IGBST 2012, p. 34; Bjornlie *et al.* 2014a, p. 184). Inside the DMA, the population has stabilized since 2002 and is exhibiting density-dependent population regulation (van Manen *et al.* 2016, entire). Although humans are still directly or indirectly responsible for the majority of grizzly bear deaths, this source of mortality is effectively mitigated through science-based management, State regulations, careful population monitoring, and outreach efforts. Since 1975, no grizzly bears have been removed from the GYE for commercial, recreational, scientific, or education purposes. Although the States may choose to institute carefully regulated grizzly bear hunting outside of the national parks, it would be within scientifically determined sustainable levels to maintain the population in the long term and would not occur if other sources of human-caused mortality were excessive. Therefore, based on the best available information and State regulatory mechanisms that will limit total mortality levels within the levels detailed in tables 2 and 3 and that these regulatory mechanisms will continue into the foreseeable future, we conclude that disease, natural predation, and human-caused mortality do not constitute threats now or in the foreseeable future.

The importance of regulatory mechanisms and effective wildlife management infrastructure to large carnivore conservation cannot be understated, as described under *Factors A and B and C Combined* (see Linnell *et al.* 2001, p. 348). Before publication of this final rule, the regulatory mechanisms in place include National Park Superintendent's Compendia, the USFS Amendment for Grizzly Bear Habitat Conservation for the GYE National Forests, and State and Tribal commission regulations controlling mortality as described under *Factors A and B and C Combined.* The management infrastructure is already in place and described in the 2016 Conservation Strategy. Because the signatory agencies to the 2016 Conservation Strategy are the same agencies that have been managing grizzly bear habitat, population, and monitoring for the last 40 years, the management transition would be minimal. Existing regulatory mechanisms will ensure the GYE grizzly bear population continues to meet the recovery criteria. Therefore, we conclude that the existing regulatory mechanisms are adequate to maintain a healthy and recovered population of grizzly bears into the foreseeable future and do not pose a threat now, or in the foreseeable future.

Other factors under *Factor E* we considered that could become threats to the GYE grizzly bear population included: (1) Genetic health, (2) potential changes in food resources, (3) climate change, (4) catastrophic events, and (5) human attitudes toward grizzly bear recovery. Essentially, the management response to all of these potential threats would be to limit human-caused mortality through conflict prevention and management as well as managing discretionary mortality. Because of the manageable nature of these potential threats through conflict prevention and response efforts and the large amount of suitable, secure habitat within the GYE, we do not expect other natural or manmade factors to become threats to the GYE grizzly bear population.

Many of the threats faced by grizzly bears are interrelated and could cumulatively impact the GYE grizzly bear population through excessive grizzly bear mortality. While these numerous stressors on grizzly bear persistence are challenging to conservation, our experience demonstrates it is possible for large carnivore conservation to be compatible with them (Linnell *et al.* 2001, p. 48), particularly given the rigorous scientific monitoring protocols established for the GYE grizzly bear population. There will always be stressors to the GYE grizzly bear population, but if these are not causing the population to decline, we do not consider them to threaten the long-term persistence of the population.

Summary of and Responses to Peer Review and Public Comment

In the proposed rule published on March 11, 2016 (81 FR 13174), we requested that all interested parties submit written comments on the proposal by May 10, 2016. We also

contacted appropriate Federal and State agencies, Tribes, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. A newspaper notice inviting general public comment was published in the Bozeman Chronicle on March 27, 2016, the Cody Enterprise and the Casper Star-Tribune on March 29, 2016, and the Jackson Hole News & Guide on March 30, 2016. On September 7, 2016 (81 FR 61658), we reopened the comment period on the proposed rule until October 7, 2016, to make available comments from five peer reviewers and additional supplemental material. We held two public meetings followed by public hearings, one in Cody, Wyoming (April 11, 2016), and another in Bozeman, Montana (April 12, 2016). All substantive information provided during the comment periods has either been incorporated directly into this final determination or addressed in the more specific responses to comments below.

A number of commenters, including peer reviewers, Federal agencies, and the States, provided new information or clarifications on information presented in the GYE proposed delisting rule (81 FR 13174, March 11, 2016) and its supporting documents. Categories of new or clarified information include corrections of discrepancies between the proposed rule and draft 2016 Conservation Strategy (*e.g.,* table 2 clarifies that mortality limits apply to total mortality), the discussion of carrying capacity, our analysis of density-independent and density-dependent effects on GYE grizzly bear population dynamics, our use of ''cause'' versus ''association'' in our density-dependent analysis, and range versus distribution (please see the *Population Ecology—Background* section above). This new or clarified information has been incorporated, as appropriate, into this final rule, the 2016 Conservation Strategy (YES 2016a, entire), and the Recovery Plan supplement (USFWS 2017, entire). In the proposed and final rules, we presented data as of 2014, and did not update in the five-factor threats assessment because: (1) We would not have been able to update all of the data given the amount of time available to do so between the proposed rule and this final rule, and (2) intensive monitoring has been ongoing since prior to 2014 (*e.g.,* habitat management has been in compliance with the 1998 baseline, the three demographic recovery criteria have been maintained, and monitoring has not detected a change in the population trajectory); therefore, including data since 2014 would not have changed our assessment. In response to specific public comments, we did respond using the most recent available data. When talking about data, we mean raw data that has not been published. We did, however, include all relevant peer-reviewed publications since 2014 and up to this final rule.

General Issues

Issue 1—Several commenters submitted comments on topics related to other issues not specific to the GYE delisting proposal. These issues include (a) general criticism of the Act (litigation driving regulatory decisions, failure to delist species exceeding recovery criteria could jeopardize the Act, suggested updates to the Act, funding of the Act should be reconsidered); (b) a desire for removing colonial occupation and restoring the continent to self-sufficiency, which would allow wildlife to flourish; (c) simpler methods for uploading comments on regulations.gov; (d) the potentially negative impact of delisting on tourism and the local economy; (e) the negative impact to ecosystem function if grizzly bears decline and the resulting trophic cascade, and other species' conservation; and (f) delisting means the GYE is no longer a true wilderness and true wilderness areas must be protected in perpetuity.

Response—All of these comments are outside the scope of this final delisting rule and will not be addressed here. Substantive comments related to the conservation of the other grizzly bear populations would be addressed during the Recovery Plan revision process for those populations, should we decide revisions are necessary.

Issue 2—Several commenters expressed general concerns related to grizzly bear management including: (a) Consideration, analyses, and commitments to recovery of grizzly bear populations elsewhere in the lower 48 States; (b) ethical concerns related to hunting generally or ''trophy hunting'' of grizzly bears; and (c) delisting could prematurely halt the current development of local tolerance towards grizzly bears and their habitat expansion.

Response—This listing action is specific to the grizzly bear population in the GYE and, therefore, affects only the legal status of grizzly bears within the GYE. In other words, when this regulation takes effect, grizzly bear populations occurring outside of the boundary of the GYE DPS will remain listed as a threatened species under the ESA. Therefore, consideration and analyses of grizzly bear populations elsewhere in the lower 48 States is outside the scope of this rulemaking.

While we respect the values and opinions of all commenters, the Act does not allow us to factor ethical objections to hunting into our delisting decision. Section 4(a)(1) of the Act specifies that we shall determine whether any species is threatened or endangered because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Section 4(b)(1)(A) further specifies that we shall make such determinations based solely on the best scientific and commercial data available.

The best scientific and commercial data available indicate that the GYE grizzly bear population is recovered and no longer meets the definition of a threatened or endangered species. However, we acknowledge tolerance of grizzly bears remains a concern in some areas. The 2016 Conservation Strategy contains a strong Information and Education (I&E) program component that will continue efforts to improve local tolerance towards the species.

Delisting Process and Compliance With Applicable Laws, Regulations, and Policies

Issue 3—Several commenters expressed concern that the opportunity for public involvement was inadequate. Specifically, the commenters requested longer public comment periods, more public hearings at additional locations across the country, timely access to all necessary data and materials presented at an appropriately accessible level, and accommodations for the visually impaired and those without internet access to ensure their ability to provide comments on the rule.

Response—We appreciate the time and thought put into comments on the proposed rule to delist the GYE grizzly bear. Collectively, we believe the public had ample opportunity for input, as explained below. We followed Service practice and policy in managing the public comment process. We provided multiple opportunities and avenues for public involvement. Notifications of comment periods, meetings, and hearings were provided in the proposed rule, which was published in the **Federal Register**, posted on our Web site, and publicized in newspapers. These postings were compliant with the

requirements of Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794(d)). We also provided access information for persons using a telecommunications device.

The public comment period on the proposed rule was open for a total of 90 days, during which time we received more than 665,000 comments. We offered a variety of options for submitting comments; the public could submit their comments electronically, using a specified Web site, or in hard copy, via U.S. mail or hand delivery.

As mentioned above, we also held two public meetings and public hearings in Cody, WY, and Bozeman, MT, where verbal or written comments could be submitted. These two cities were selected because of their proximity to the GYE. We declined to hold additional public hearings because we satisfied section 4(b)(5)(E)'s statutory requirement that we hold at least one public hearing and the substantial cost associated with conducting public hearings. Although we appreciate the public's desire to give public testimony, oral and written comments are given the same consideration in our process. We again provided access information for persons using a telecommunications device. In our notifications of comment periods, meetings, and hearings, we stated that persons with disabilities wanting to participate in a public meeting or hearing, including the need for American Sign Language or English as a second language interpreter, could be accommodated.

Issue 4—Commenters suggested that a second round of peer review and additional public comment period was needed once a final 2016 Conservation Strategy and final regulatory mechanisms were available; they noted that reviewers were asked to answer questions about the adequacy of regulatory mechanisms without these final documents, casting doubt on the ''utility and accuracy'' of their review and that ''significant changes'' being made to the draft 2016 Conservation Strategy released in March 2016 could alter the opinion of peer reviewers and the public on the adequacy of the management described in these documents. Some commenters referred to previous promises at Yellowstone Ecosystem Subcommittee (YES) meetings for additional public comment on the final 2016 Conservation Strategy. Finally, one commenter could not understand why the Service re-released a proposed rule for additional public comment with ''fundamental issues still in debate and unresolved.''

Response—We gave the public two opportunities to comment on the proposed rule, including an opportunity to comment on its content in light of the revised State regulatory mechanisms, the draft 2016 Conservation Strategy, and the peer review. The public and peer reviewers also had an opportunity to provide feedback on the draft 2016 Conservation Strategy during the same public comment periods as the proposed rule. We made no promises to allow additional comment from the public at the YES meetings. Changes to the draft 2016 Conservation Strategy took into account public comments. The final rule and the final 2016 Conservation Strategy are a logical outgrowth of the considerations in the peer review and in the more than 665,000 public comments we received. Changes to the 2016 Conservation Strategy were made to remove inconsistency with the proposed rule and to improve clarity, but there were not significant changes to the tenets of the strategy from the draft to final. We do not believe that fundamental issues are still in debate; we believe the best available science clearly shows that the GYE population is recovered.

Issue 5—Commenters expressed concerns that the consideration the Service gives public comments is a flawed process designed to ensure that only some comments are considered. They stated that the Service considers only comments that are based on a scientific rationale and ignores those that were based on general public opinion or contained insubstantial content, and further suggested we did not consider these comments because we disagreed with their content. Other commenters requested a more prominent role in the recovery and delisting process and more opportunity to communicate concern for the future of the species.

Response—We fully considered and evaluated all public comments received during the comment periods and public hearings, and evaluated all comments, whether they agree with or disagree with our proposal.

The Act requires the Service to make a decision based solely on the best available scientific and commercial information available (section 4(b)(1)(A)) when determining if a species meets the definition of endangered or threatened. Substantive comments raising scientific, legal, and policy issues are the most relevant for consideration in our determination. We focused our attention on unique comments that provide substantive feedback on potential errors or oversights in our analyses. We appreciate and consider additional data or substantive remarks, with supporting documentation, that broaden our understanding of whether grizzly bears meet the definition of a threatened or endangered species under the Act. We considered all scientific and commercial information included in the public comments, and incorporated this information into this final rule as appropriate.

Issue 6—We received public comments that the public opposed the previous delisting effort and encouraged us to address all claims made in challenges to the 2007 proposed delisting including issues related to: Habitat loss, current habitat protections, funding for post-delisting conservation efforts, lag effects, failure to account for hunting mortality, political interference, peer review, and disease and predation.

Response—All relevant topics related to these comments are addressed in the specific issues below.

Issue 7—Multiple commenters requested we release the National Environmental Policy Act (NEPA) documentation associated with the proposed rule to delist the GYE population of grizzly bears.

Response—This delisting rule is promulgated under section 4(a) of the Act and consequently is exempt from NEPA procedures. Our decision that NEPA does not apply under section 4(a) is based on the reasoning in *Pacific Legal Foundation* v. *Andrus,* 657 F.2d 829 (6th Cir. 1981) that we cannot consider environmental impacts beyond those addressed by the five factors described in section 4(a) and must use only the best scientific and commercial data available in evaluating those factors. After this ruling, we published a determination in the **Federal Register** (48 FR 49244, October 25, 1983). Therefore, this delisting decision is based solely on the five-factor analysis described in section 4(a), and there is no NEPA documentation required.

Issue 8—Several commenters expressed concerns over a perceived lack of collaboration among the Service and other stakeholders in the delisting process and requested increased collaboration among the Service, NGOs, general public, Tribes, States, Interagency Grizzly Bear Study Team (IGBST), National Park Service (NPS), U.S. Forest Service (USFS), and Canada. Commenters suggested that increased collaboration would allow for the synchronization of multiple conservation efforts prior to delisting, ensure the concerns of all associated organizations are addressed, and enhance support for the proposal. Commenters expressed concerns that the long-term conservation efforts will be diminished if the species is delisted

on the current timeline without sufficient collaboration among partners. They especially expressed that we should more adequately address the NPS' concerns, that the NPS should have a larger role in the delisting decision, and that the NPS should have greater involvement in species management outside of (and especially adjacent to) park boundaries.

Response—The Service has regularly coordinated with a wide variety of stakeholders through the more than 40 years of the grizzly bear recovery program. Please see the *Recovery Planning and Implementation* section of this rule for a description of the role of Federal, Tribal, State, and local agencies involved in the formal interagency groups that collaboratively help guide grizzly bear management in the GYE. In addition, these agencies worked with local landowners, NGOs, and other interested parties to implement the 1993 Recovery Plan. It is through these successful partnerships that the GYE has recovered and no longer meets the definition of a threatened or endangered species. These important partnerships will continue through the implementation of the 2016 Conservation Strategy.

The Service appreciates the long-standing efforts of all of our partners in the GYE's recovery; however, the decision on whether or not to list, delist, or reclassify species under the Act remains the sole regulatory responsibility of our agency. The NPS only has jurisdiction to manage natural resources within the Park boundaries, but often collaborates with adjacent landowners on wildlife-specific issues. NPS manages approximately 39 percent of lands within the PCA. Please see Issue 65 for a discussion about hunting on and adjacent to NPS lands and Issue 82 about inclusion of the NPS in annual meetings with the States allocating discretionary mortality.

Issue 9—Commenters expressed confusion and concerns over the functionality and role of the YES and the YGCC. Commenters were concerned that the role and influence in the delisting process given to these committees far outweighed that of the public and other organizations.

Response—Upon delisting, the YGCC will take the place of YES. Whereas the primary objective of YES was interagency coordination to achieve recovery, the primary objective of the YGCC will be interagency coordination to maintain a recovered grizzly bear population in the GYE through implementation of the 2016 Conservation Strategy. The IGBST will continue their monitoring of the GYE grizzly bear population and provide this information to the YGCC and the States so that the States may make scientifically informed decisions regarding population management. Please see the 2016 Conservation Strategy (YES 2016a, pp. 96–103) at *https://www.fws.gov/mountain-prairie/species/mammals/grizzly/ConservationStrategy grizzlybearGYA.pdf* for further details about membership and primary activities of the YGCC. Although the proposed and final rules are solely within the purview of the Service, conservation strategies serve as guiding documents for post-delisting management and monitoring by the multiple State and Federal agencies responsible for these tasks. The Conservation Strategy ensures that the regulatory mechanisms and coordinated management that led to recovery will be maintained following delisting. Post delisting, mortality management will be the responsibility of State fish and wildlife agencies.

Accordingly, it is appropriate that they would be responsible for articulating their post-delisting management plans. Likewise the Federal land management agencies will be responsible for habitat management. Our role is to analyze these commitments and ensure they will allow the species to remain recovered. Please see Issue 5 for further discussion about the processing and consideration of public comments.

Issue 10—Many commenters raised concerns about our peer review process. First, commenters expressed doubt as to the five peer reviewers' professional ability to comment on the proposed rule since only one peer reviewer specialized in grizzly bears, while the other four focused on polar bears or black bears, which differ ecologically and behaviorally. One commenter asked why Dr. David Mattson was not asked to review.

Second, commenters expressed concern about peer reviewer selection and suggested we had not adequately disclosed this process. Some commenters suggested that our peer reviewers had a conflict of interest because the Service's contractor who facilitated their selection works in the oil and gas industry rather than wildlife science, while other commenters suggested that the peer reviewers had a conflict of interest since they all hunt or trap. Some commenters claimed that documents released under the Freedom of Information Act indicated we ''hand-picked reviewers'' to ensure a favorable review, subverting the validity and independence of the peer review process, and that we purposefully selected reviewers that were not grizzly bear experts, since the majority of grizzly bear experts would have been opposed to our proposed action, according to a survey from Ohio State University. Another commenter suggested that we could not legally use a contractor for the peer review process because: (1) The contractor is not disclosing the process to the public; (2) we cannot outsource the preparation of the Administrative Record; and (3) it violates a 2004 OMB policy, ''Final Information Quality Bulletin for Peer Review'' (70 FR 2664, January 14, 2005), and a 1994 Service policy, ''Interagency Policy for Peer Review in ESA Activities'' (59 FR 34270, July 1, 1994). One commenter suggested that only a National Academy of Sciences panel would be adequate for performing review of the rule.

Third, commenters stated that we did not follow up with the peer reviewers to ask them additional questions, noting that not doing so suggested that we did not give the peer review or our delisting decision enough thought. Another commenter suggested that this situation implied the need for another round of peer review (see Issue 4). Fourth, one commenter took issue with the fact that we did not share with the public which peer reviewer authored each review. Finally, one commenter thought we did not give the peer reviewers enough time to review the proposed rule and associated documents.

Response—To ensure the quality and credibility of the scientific information we use to make decisions, we follow a formal ''peer review'' process for influential scientific documents. This process follows the guidelines for Federal agencies spelled out in the Office of Management and Budget (OMB) ''Final Information Quality Bulletin for Peer Review'' (70 FR 2664, January 14, 2005). The Service updated its policy guidance for conducting such scientific peer reviews on listing and recovery actions in August 2016; however, the proposed rule was sent out for peer review prior to that new policy. The 2005 guidelines leave selection of an appropriate peer review mechanism up to the agency's discretion, but require the process to be transparent, that reviewers possess the necessary expertise, and that the process addresses reviewers' potential conflicts of interest and independence from the agency. The names of reviewers may be disclosed publicly or may remain anonymous; however, anonymous reviews are standard practice within the Service in order to encourage candor.

We chose to contract the peer review out due to the controversial nature of our decision. Nothing in the current Service peer review guidance and policy prohibits the Service from doing so. As part of this process, we drafted a statement of work to the peer-review contractor, which included criteria: ''The independent peer reviewers shall be experienced senior-level ecologists, bear biologists, or population modelers, and bear managers who have previously conducted similar reviews or regularly provided reviews of research and conservation articles for the scientific literature. Reviewers must be well-versed in the demographic management of mammals, preferably bears or other carnivores.'' We also identified potential conflicts of interest, including: employment or affiliation with the Service, the States of Montana, Wyoming, or Idaho, the IGBST, or the Western Governors Association; those who have offered a public opinion or a statement either for or against delisting; and those who are directly or indirectly employed by or associated in any way with any organization that has either litigated the Federal Government concerning grizzly bears or wolves or taken a position on one side or the other about recovery and delisting of grizzly bears or wolves. Our statement of work also included topics and questions for the reviewers to consider and deliverables, including a proposed timeline, original scientific reviews, and a Complete Official Record.

The contractor then selected the reviewers based on our statement of work. We do not know why any particular person was not chosen, such as Dr. David Mattson; however, we do know that those reviewers chosen did meet the above criteria. Neither we nor the contractor handpicked reviewers hoping to get a favorable review, as that would be counterproductive to the Act's requirements that we base our decisions based on the best available data.

Peer reviewers are generally selected for their expertise on the particular species, closely related species, relevant threats or conservation actions, or other relevant topics (*e.g.,* landscape ecology). To the extent that a member of the National Academy of Science has relevant expertise, they could be a peer reviewer, but that organization is not the only source of adequate or appropriate peer review. Peer reviewers were asked not to provide recommendations on the species' listing determination; rather they were asked to comment specifically on the quality of any information and analyses used or relied on in the document; identify oversights, omissions, and inconsistencies; provide advice on reasonableness of judgments made from the scientific evidence; ensure that scientific uncertainties are clearly identified and characterized, and that potential implications of uncertainties for the technical conclusions drawn are clear; and provide advice on the overall strengths and limitations of the scientific data used in the document.

The peer reviewers were asked to provide comments within the open public comment period to allow for the public to access and comment on, should they choose, the peer reviewers' comments. No peer reviewers requested additional time for review. The peer reviewer comments were posted in regulations.gov under the docket for this rulemaking. As previously noted, the first comment period was open for 60 days, and a second comment period was open for an additional 30 days, which provided ample time for the public to review the proposed rule and supplemental documents and provide comments. Once the process is complete, we take into consideration the context of all comments, including those from peer reviewers, in our evaluation of the substantive information provided.

Using a contractor for peer review does not indicate we are outsourcing the administrative record for this decision, as the administrative record comprises many documents throughout the listing determination process and compilation of the administrative record remains the Service's obligation. The Service is maintaining the decision file and will be preparing an administrative record per the Department of the Interior's guidance for compiling decision files and administrative records (282 FW 5).

Issue 11—Many commenters expressed general concern that this rule to delist the GYE grizzly bear population allowed ''politics and private interests to trump science,'' that we have been ''bought,'' that we are ''biased,'' that our process is ''politically driven,'' and that we have rushed the process for the purposes of political expediency (*e.g.,* by forgoing public involvement on the 2016 Conservation Strategy and sacrificing needed updates to state management plans). Commenters suggested the need for a ''scientific integrity review'' into potentially undue political influence on the Service's decision-making process. Claims of this inappropriate influence included that: (1) The Service's Director and State governors used ''under the table agreements'' to set the mortality limits in the rule, recovery plan supplement, and 2016 Conservation Strategy; (2) the former grizzly bear recovery coordinator's studies were biased and not open to peer or public review and that he was unable to be objective regarding the delisting; (3) Service managers bullied staff biologists to delist the GYE grizzly bear population; (4) there was political interference with the 2015 IGBST report on grizzly bear mortality; (5) the Service is a pro-hunting organization and Service staff involved in the delisting process have ties to hunting organizations, oil and gas companies, or initiatives working to exterminate wolves; (6) the States pressured the Service to use population estimates that produce the maximum number of bears; (7) the Service is only proposing to delist the GYE population (and not the ''larger northern population'') because of the influence of hunting, oil, gas, mining, and property development lobbies; (8) industrial interests on the YES/YGCC inappropriately influenced the delisting proposal and will inappropriately influence any future changes to the 2016 Conservation Strategy; and (9) a 2015 Union of Concerned Scientists Report suggested a dearth of ''scientific integrity'' at the FWS due to ''political interference.''

Lastly, some commenters suggested that the delisting decision was a ''political stunt to weaken the Endangered Species Act,'' referencing recently proposed legislation that would prevent litigation from overturning delisting decisions, thus ''denying opponents [of delisting] due process.'' On the other hand, one commenter suggested that delisting the grizzly bears was a stunt to save the Act from legislative destruction.

Conversely, a number of commenters expressed support for the Service's scientific integrity and the validity and breadth of the data the Service used in the decision-making process.

Response—There is no data or evidence of political interference or bias. While we respect and understand that some members of the public disapprove of this decision, it is the appropriate decision because the GYE grizzly bear no longer meets the definition of a threatened or endangered species, based on a thorough analysis of the best available scientific and commercial information. We are compelled to make this delisting decision under the statutory requirements of the Act. Furthermore, the IGBST, as well as senior scientists in the agency, recommended to senior leadership within the agency that moving forward with delisting was scientifically appropriate. We will respond to each specific claim of undue influence below.

First, commenters claimed that the Service's Director and State governors used ''under the table agreements'' to set the mortality limits in the rule, recovery plan supplement, and 2016 Conservation Strategy. The mortality limits are set in the recovery plan supplement (demographic recovery criterion #3) and carried over into this rule and the 2016 Conservation Strategy. Section 4 of the Act provides direction for developing and implementing endangered species recovery. The Section gives the Service the ability to procure the services of appropriate public and private agencies and institutions, and other qualified persons. We discussed mortality limits with the States because they are the agencies that will be directly responsible for implementing them. More importantly, the mortality limits in the recovery criteria are scientifically defensible and will insure that the GYE grizzly bear population within the DMA will be maintained around the 2002 to 2014 population size (see Issue 66 for further discussion on the mortality rates). Throughout the more than 40 years of grizzly bear recovery, the Service has collaborated closely with state agencies to ensure positive conservation outcomes for grizzly bears and effective, coordinated management. This collaboration is partly responsible for a recovered GYE grizzly bear population. This collaboration continued throughout the delisting process to ensure effective post-delisting management and will persist after delisting through the Yellowstone Grizzly Bear Coordinating Committee.

Second, commenters suggested that the former grizzly bear coordinator's studies were biased and not open to peer or public review and that he was unable to be objective regarding the delisting. The delisting determination used the best available scientific and commercial data to come to the conclusion that grizzly bears should be removed from the list of threatened and endangered wildlife and plants. The Service relied on literature from a broad range of scientists; this literature included peer-reviewed studies from Dr. Chris Servheen, former grizzly bear recovery coordinator for the Service, but also research from other scientists. This broad range of peer-reviewed sources indicated that grizzly bears in the GYE were recovered and would remain so after delisting.

Third, commenters claimed that Service managers bullied staff biologists to delist the GYE grizzly bear population. Commenters provided no evidence of any alleged ''bullying'' of staff biologists. The Service acknowledges that its former grizzly bear coordinator, Dr. Chris Servheen, may have concluded that the Service did not always agree with his recommendations. However, there was no ''bullying.'' The delisting recommendation came from staff biologists. There were a number of issues worked out between Serve staff and management. Internal agency disagreement and debate are expected with a delisting rule for a controversial species like grizzly bears. The decision to delist the GYE population of grizzly bears was based on the best available scientific and commercial data available. Service biologists presented this information, including data on grizzly population trends and State management regulations, to Service leadership to inform their decision-making about the status of grizzly bears in the GYE. The Service's decision-making process provides opportunity for staff biologists who are species experts to outline all relevant information, ask questions, and provide recommendations.

Fourth, commenters claimed that there was political interference with the 2015 IGBST report on grizzly bear mortality because publication of the report was delayed. There is no annual due date for this report, and while it is usually published midsummer, sometimes there are delays. The delays in the release of the 2015 IGBST report on grizzly bear mortality were not a result of political interference but a combination of the IGBST team leader being on detail as the Acting Center Director of the USGS Northern Rocky Mountain Science Center for three months, transitions within the IGBST, and scientific presentations, which delayed finalization of the report. We had all relevant data from this report available to inform our decision-making process about the status of grizzly bears. Considering the relevant content of this report, we believe that grizzly bears are recovered and will remain so for the foreseeable future.

Fifth, commenters suggested that the Service is a pro-hunting organization and Service staff involved in the delisting process have ties to hunting organizations, oil and gas companies, or initiatives working to exterminate wolves. The Service supports hunting as a form of wildlife-dependent recreation and as a useful element in a suite of management strategies. However, the Service is not an agency whose purpose is to promote hunting or hunting interests; the Service mission is working with others to conserve, protect, and enhance fish, wildlife, plants, and their habitats for the continuing benefit of the American people. While hunting can be an essential element of conserving wildlife and their habitats and can be a benefit that wildlife provide to the American people, the Service considers a broad range of factors and benefits when managing species and making decisions supportive of this mission. Furthermore, very little of the Service's budget and none of the Endangered Species program's budget comes from hunting revenue. While many Service staff support or contribute to a variety of causes in their personal capacity, Service ethics rules and guidelines (for example, 212 FW 1 through11), Departmental Regulations (for example, 5 CFR 3501.105), and government-wide laws and regulations (for example, 18 U.S.C. Sections 201–209; 5 CFR 2635.502) ensure these affiliations do not impact or bias their decision-making and management.

Sixth, commenters claimed that the States pressured the Service to use population estimates that produce the maximum number of bears. This unsupported accusation is false. The population estimates the Service used in its delisting determination (the model-averaged Chao2 population estimator) is based on the best available commercial and scientific data available and not States' individual preferences. Moreover, the model-averaged Chao2 population estimator is a relatively conservative estimate of the number of bears on the landscape in the GYE and likely underestimates the actual number of bears (Schwartz *et al.* 2008, figure 5). Other population estimators considered by the Service (see Issues 28 and 31), but determined not to be accurate in detecting population trend, yielded higher population numbers.

Seventh, commenters claimed that the Service is only proposing to delist the GYE population (and not the ''larger northern population'') because of the influence of hunting, oil, gas, mining, and property development lobbies. The recovery of grizzly bears has always been focused around six different recovery zones. Each recovery zone has different recovery needs and criteria based on the biology of the species in that area and the relevant stressors. Thus, delisting of the bears in each recovery zone may occur on a different timeline as the populations meet unique recovery criteria. Based purely on the best available scientific and commercial data available, the population of grizzly bears in the GYE was the first to achieve recovery and warrant delisting. As other populations achieve this milestone, as determined by the best available scientific and commercial data

available, the Service will proceed with proposing to delist these populations.

Eighth, commenters suggested that industrial interests on the YES/YGCC inappropriately influenced the delisting proposal and will inappropriately influence any future changes to the 2016 Conservation Strategy. The Service has regularly coordinated with a wide variety of stakeholders through the more than 40 years of the grizzly bear recovery program. Please see the *Recovery Planning and Implementation* section of the final rule for a description of the role of Federal, Tribal, State, and local agencies involved in the formal interagency groups that collaboratively help guide grizzly bear management in the GYE. In addition, these agencies worked with local landowners, NGOs, and other interested parties to implement the 1993 Recovery Plan. The Service also met with a broad variety of stakeholders throughout the delisting process, including environmental NGOs. It is through these successful partnerships that the GYE has recovered and no longer meets the definition of a threatened or endangered species. These important partnerships will continue through the implementation of the 2016 Conservation Strategy to ensure a wide variety of interested parties can contribute to the continued success of grizzly bear management following delisting. In addition, any changes to the 2016 Conservation Strategy will be open to public comment.

Ninth, commenters referenced a 2015 Union of Concerned Scientists Report, which suggested a dearth of ''scientific integrity'' at the FWS due to ''political interference.'' The Union of Concerned Scientists surveyed scientists at four federal agencies, including the Service, on ''the state of scientific integrity at their agencies, their ability to communicate with colleagues and the public, and overall agency effectiveness'' (Union of Concerned Scientists 2015, p. 4). This survey included biologists Service wide and did not include information on the particular work being conducted by survey participants. It did not directly address grizzly bears. The Service has a rigorous policy on scientific integrity that guides the agency's work and decision-making (212 FW 7). The policy states, ''Scientific and scholarly information that we consider in our decision-making must be robust, of the highest quality, and the result of the most rigorous scientific and scholarly processes as can be achieved. Most importantly, it must be trustworthy. We must establish and maintain integrity in our scientific and scholarly activities because this information is a critical factor for making public policies.'' In addition, delisting decisions are subject to scientific peer review according to the Service's peer review policy set forth in the Office of Management and Budget ''Final Information Quality Bulletin for Peer Review'' (70 FR 2664, January 14, 2005). The Service is committed to using the best available scientific and commercial data available in our delisting decisions, as required by the Endangered Species Act. For all of these reasons, the Service does not believe a scientific integrity review is needed.

The Service has been considering delisting of the GYE grizzly bear population for over a decade and previously published a final rule to delist this population in 2007 (72 FR 14866, March 29, 2007). As described in the Background section, that final determination was vacated by the Montana district court in *Greater Yellowstone Coalition* v. *Servheen, et al.,* 672 F.Supp.2d 1105 (D. Mont. 2009), and the vacatur was affirmed by the Ninth Circuit Court of Appeals in *Greater Yellowstone Coalition* v. *Servheen, et al.,* 665 F.3d 1015 (9th Cir. 2011). During those intervening years, the Service has continued to work with its partners and the public to ensure GYE grizzly recovery. This delisting rule is the culmination of a process that began over a decade ago, and it is by no means rushed.

Geographic Scope of Recovery and Delisting Issues

Issue 12—The Service received comments indicating that the proposed habitat protections and demographic standards are too limited in geographic scope. Commenters took specific issue with the scope of our threats, or ''five factor'' analysis. They claimed that we failed to fulfill the requirements in section 4(a)(1) of the Act since we only analyzed the importance of threats inside the DMA; commenters suggested that the threats analysis should not be ''limited to suitable habitat.'' These commenters requested we provide a more thorough analysis that considers threats and their impact on grizzly bears in the entire GYE DPS because invisible boundaries cannot be used to classify the health of a population.

Response—Our threats analysis focused on those portions of grizzly bear range that currently contribute meaningfully to the GYE grizzly bear population or have the potential to contribute in the foreseeable future (*i.e.,* suitable habitat, as defined and discussed in the Suitable Habitat section). In total, grizzly bears currently occupy 58,314 km^2 (22,515 mi^2) of land within the GYE DPS boundaries. Seventy-two percent of the area occupied occurs within areas we consider suitable habitat, 28 percent of the area occupied is in unsuitable habitat, and 77 percent of occupancy is within the DMA boundaries. The DMA provides more than enough suitable habitat for a large, robust, healthy, and viable population and will continue to do so for the foreseeable future. Put another way, the DMA contains sufficient numbers and distribution of reproductive individuals to maintain the population's recovered status (*i.e.,* does not meet the definition of a threatened or endangered species). Additional occupancy beyond this area is above what is needed to maintain recovery. Therefore, we believe focusing on this area is a reasonable and biologically rational approach.

To the extent that this comment requests consideration of threats outside of the suitable habitat, we respond as follows (considering Factors A, B, C, D, and E). Although grizzly bears once occurred throughout the area within the GYE DPS boundaries (Stebler 1972, pp. 297–299), records indicate that even in the early 19th century, grizzly bears were less common in these eastern prairie habitats than in mountainous areas to the west and south (Rollins 1935, p. 191; Wade 1947, p. 444). Today, these habitats are no longer biologically suitable for grizzly bears as they lack adequate natural food resources and land use changes have altered the suitability of the habitat for grizzly bear persistence (considering Factors A, B, C, D, and E). These marginal, peripheral areas are either unoccupied or might in some instances have limited occupancy due to dispersal from core source population within the PCA, DMA, and suitable habitat. While grizzly bears that do establish or move into these unsuitable habitats will face a reduced probability of persistence (considering Factors A, B, C, D, and E), these bears will constitute a small percentage of the population and, thus, are of minimal importance to the sustainability of the overall population. Such peripheral impacts will not compromise the viability of the GYE population. Impacts to GYE bears in unsuitable habitat will not and do not singularly, or in combination with other factors, cause the GYE population to become in danger of extinction nor likely to become so within the foreseeable future in all or a significant portion of its range.

Issue 13—Many commenters, including some with differing viewpoints on the status of the Northern Continental Divide Ecosystem (NCDE)

grizzly bear population, wanted clarification on what delisting for the GYE would mean for other grizzly bear populations. One commenter requested clarification on how this rule would distinguish grizzly bears that are a part of the GYE population from those who might be part of a different population located in Idaho, Montana or Wyoming.

Response—Upon delisting of the GYE grizzly bear population, all grizzly bears in the lower 48 outside of the GYE DPS boundaries will continue to be fully protected under the Act. DNA samples are opportunistically collected from all grizzly bears trapped for research or management and all known mortalities. Genetic differences between GYE grizzly bears and other grizzly bear populations allow us to detect immigration and emigration from the GYE. As stated in Issue 2, the management and potential status of other grizzly bear populations is outside the scope of this final rule. That said, a draft Environmental Impact Statement (EIS) that examines recovery options for grizzly bears in the North Cascades was published in the **Federal Register** on January 13, 2017 (82 FR 4336). Between 1993 and 1999, we issued warranted but precluded findings to reclassify grizzly bears as endangered in the Cabinet-Yaak (58 FR 8250–8251, February 12, 1993; 64 FR 26725–26733, May 17, 1999), and the Selkirk Ecosystems (64 FR 26725–26733, May 17, 1999). However, as of 2014, both the Selkirk and Cabinet-Yaak populations were reclassified as threatened (79 FR 72440, December 5, 2014) because of improving population trends (79 FR 72488). However, the Service's determination about Cabinet-Yaak bears has been challenged in *Alliance for the Wild Rockies* v. *Jewell, et al.,* case no 9:16–cv–00021 (D. Mont.) The NCDE grizzly bear population is likely biologically recovered; the IGBC NCDE subcommittee drafted a Conservation Strategy in 2013 that was published by the Service in the **Federal Register** for public comment and peer review.

Issue 14—One commenter requested additional clarification on how we define range and distribution of grizzly bears. He asked how heavily an area needs to be used to be considered part of a species' range and what disqualifies an area from being part of a species' range (*e.g.,* when Colorado was removed from the species' identified range a few decades ago). This commenter also asked whether the term ''distribution'' is synonymous with ''range,'' how distribution is defined, and how much of the current GYE population is contained within the current distribution.

Response—The term range generally encompasses the outer limits of a species' historical or current occupancy based on the data from reliable published scientific literature, submitted manuscripts, and species' experts; occurrence data; and analysis. In the proposed rule we used distribution, occupancy, occurrence, and current range interchangeably, and for this final rule we consistently use current range. We also discuss historical range in this final rule. A species may be distributed in greater or lesser numbers within its current range, depending on season, food availability, or other biological needs. Therefore, we continue to use the term distribution as it relates to food resources and in reference to recovery criterion #2 (relating to the number of bear management units occupied by females with young).

Working With Tribes and Tribal Issues

Issue 15—A number of commenters stated that (a) Native American interests and concerns were not adequately addressed in the rule; (b) more than 100 Tribal nations oppose the delisting; (c) we did not adequately consider the cultural, spiritual, and ecological significance of the grizzly bear to Native American Tribes, thus violating Executive Orders, Secretarial Orders, and Federal laws (including the American Indian Religious Freedom Act); (d) we did not appropriately analyze the significance of Tribal territory and treaty rights in the GYE, thus violating Tribal sovereignty; and (e) we did not fulfill our obligation under Executive Order 13175 to consult with the Tribes on the proposed rule. In addition, several commenters questioned whether all Federally recognized Tribes west of the Mississippi River (including Canadian Tribes) had been properly contacted, asserting that communications through form letters, emails, etc., are not sufficient to meet the intent of and requirement for face-to-face and government-to-government consultation. Furthermore, commenters stated that all consultations should have been conducted prior to publishing the proposed rule; commenters suggested that the delisting process should be halted until these formal consultations are completed. One commenter suggested the Service collaborate with Tribal nations prior to delisting to develop cooperative management plans for grizzly bear conservation and reintroduction on Tribal lands.

Response—We take our relationships with Tribes very seriously. In accordance with the President's memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951), E.O. 13175, and the DOI manual at 512 DM 2, we readily acknowledge our responsibility for meaningful communication with Federal Tribes. In accordance with Secretarial Order 3206 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we also acknowledge and continuously work to fulfill our responsibilities to Tribes to solicit and consider information from Tribes in our decision-making processes, to develop programs for healthy ecosystems, to recognize that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Tribal culture, and to make information available to Tribes. We did consider the American Indian Religious Freedom Act, and while we understand the concerns tribes have voiced about the potential hunting of grizzly bears, we do not agree that this final rule will burden religious practice to the extent that religious freedoms are violated because bears will still exist on the landscape and will be managed by Tribes on Tribal lands.

We regularly work with directly affected Tribes as active participants in recovery and management of the GYE grizzly bear. The Northern Arapahoe and Eastern Shoshone Tribes are participants in the YES of the IGBC as they manage nearly 4 percent of suitable habitat (1,360 km^2 (525 mi^2), although no Tribally managed land occurs within the PCA (Primary Conservation Area). The Shoshone-Bannock Tribes also participate in the YES, although they do not manage any suitable habitat. We also recognized our partnership with Tribal agencies and others in the 2016 Conservation Strategy. The YGCC will be the interagency group coordinating implementation of the 2016 Conservation Strategy and will include representatives from the Shoshone-Bannock, Northern Arapahoe, and Eastern Shoshone Tribes. Grizzly bear hunting on the Wind River Reservation will be at the discretion of these sovereign Tribes.

Beginning in April 2014, the Service sent consultation invitation letters via registered mail to the four Tribes having treaty interests in the proposed GYE grizzly bear delisting area: The Northern Arapaho, Eastern Shoshone, Northwestern Band of the Shoshone Nation, and Shoshone-Bannock Tribes. Over the next year the Service was made aware of many more Tribes having an interest in the GYE grizzly bear and expanded our efforts in explaining the

status of the grizzly bear and offering government-to-government consultation to Tribes.

On February 17, 2015, the Service sent letters offering government-to-government consultation to 26 Tribes. On June 15, 2015, the Service sent out a second round of letters to 48 tribes, offering another opportunity for consultation, followed by personal phone calls or emails from Service leadership to the 48 tribes, personally inviting them to engage in government-to-government consultation. On August 13, 2015, the Service met with the Rocky Mountain Tribal Leaders Council in Billings, Montana and invited tribal representative to engage in consultation concerning the GYE grizzly bear.

On October 29, 2015, the Service sent letters to 53 tribes, which included all Tribes, Tribal Councils, and First Nations in Canada that have contacted the Service regarding the GYE grizzly bear population. The letters invited all Federal Tribes to engage in government-to-government consultation. In addition, the letter invited Tribes to participate in an informational webinar and conference call held on November 13, 2015.

On March 3, 2016, the Service announced its proposal to delist grizzly bears in the GYE. The announcement was disseminated to all Tribes west of the Mississippi River with Tribes being notified by both email and hard copy mail. In addition, the Service announced two consultation meeting opportunities in the **Federal Register** and in the Tribal leader letters at the same time the proposed rule published. The two meetings were hosted in Bozeman, Montana and in Rapid City, South Dakota.

On March 10, 2016, the Service hosted a tribal conference call to provide an overview of the proposed delisting and discuss any questions or concerns. It was not considered government-to-government consultation. The announcement for this call was included in the March, 3rd notifications sent to Tribes.

To date, the Service has conducted ten Tribal consultations with the following Tribes: June 10, 2015: Confederated Salish and Kootenai Tribes; June 18, 2015: Blackfeet Nation Wildlife Committee; July 21, 2015: Northern Arapahoe Tribal Council; July 21, 2015: Eastern Shoshone Tribal Council; July 30, 2015: Shoshone Bannock Tribal Council; April 28, 2016: Bozeman Montana (Tribes Present at meeting: Shoshone Bannock Tribes, Northern Cheyenne Tribe, Eastern Shoshone Tribe, Northwest Band of the Shoshone); May 5, 2016: Rapid City, South Dakota (Northern Arapaho, Rosebud Sioux); November 2, 2016: Eastern Shoshone Tribe; November 16, 2016: Shoshone Bannock Tribe; April 07, 2017: Northern Cheyenne Tribal Council.

We considered issues of cultural, spiritual, and ecological importance that Tribes raised and we are sensitive to those concerns. However, the Act requires the Service to make decisions based on the biological status of the species as informed solely by the best scientific and commercial data available. That said, once this action becomes effective, Tribes will have the right to manage grizzly bears on their Tribal lands in accordance with their spiritual, cultural, and historic traditions.

Recovery Criteria and Management Objective Issues

Issue 16—Several commenters provided general concerns about the recovery criteria, which included: (1) Desires for additional discussion as to how any new population estimation method would be calibrated; (2) claims that the 1993 Recovery Plan is outdated and should be updated with the best available science; (3) suggestions that the Service consider Pyare and Berger (2003) in updating the demographic criteria; (4) concerns that any update to the Recovery Plan involved moving the ''goal post'' for recovery; (5) emphasis that the recovery criteria should be interpreted as minimums and not population goals; and (6) opinions that only the mortality limits in criterion #3 are necessary to maintain a stable population size post-delisting and the content of criteria #1 and #2 will just restrict adaptive management. Both commenters and a peer reviewer wondered whether the criteria are tied to the model-averaged Chao2 estimate or if the Service retains the discretion to change the method. Some commenters suggested additional recovery criteria be added, including: (1) A criterion to monitor the changes in food resources; and (2) a criterion linked to a declining population trend.

Response—Recovery plans are not regulatory documents; rather, they are intended to provide guidance to the Service and our partners on methods to ameliorate threats to listed species and on criteria that may be used to determine when recovery is achieved. We have updated portions of the 1993 Recovery Plan using the best available science, including a supplement to the demographic recovery criteria for the GYE grizzly bear concurrent with this rule, and agencies implementing the 2016 Conservation Strategy will continue to update it as new science and resources allow. Despite varied suggestions of additional recovery criteria (*i.e.,* consideration of Pyare and Berger (2003, pp. 70–72), criteria linked to food resources), peer reviewers largely supported the science-based approach of the recovery criteria for the GYE grizzly bear population and believe that these criteria will maintain a recovered grizzly bear population in the GYE.

Criteria #1 and #2 are important as they set forth minimums by which to measure genetic health and adequate distribution of females with young to maintain a recovered population. The 2016 Conservation Strategy commits to using the model-averaged Chao2 population estimator, for the foreseeable future, to measure the population size for criterion #3 (see Issue 28 for details regarding the Chao2 method and Issue 31 for discussion on the implementation of a new population estimator). We specify that criterion #1 is no longer dependent on a single population estimate method. Despite these updates, we note here that, as discussed above, delisting determinations are based solely on an evaluation of whether the species meets the definition of endangered or threatened due to one or more of the five factors as per section 4(a) of the Act, and while recovery criteria can inform that analysis, we do not need to update a species' recovery plan prior to the species' delisting. However, we have revised the Demographic Recovery Criteria for the GYE grizzly bear population concurrent with this final rule.

Issue 17—We received several public comments that expressed confusion and concern about specific demographic recovery criteria. On criterion #1, commenters stated: (1) A desire for further biological justification for a population objective of 500 bears, with some concerns that it too low for a population objective; (2) a request for greater emphasis that 500 grizzly bears was based on the number of individuals needed for short-term genetic health (Miller and Waits 2003) and is not a population target; (3) confusion surrounding the fact that the minimum of 500 bears applies within the entire DPS while the higher minimum of 600 bears in criterion #3 applies within the smaller DMA, with some commenters suggesting that this criterion be changed to require at least 600 bears in order to align with criterion #3, thus eliminating the confusion from setting two different population objectives, and to be consistent with the fact that 48 females with cubs (the second part of this criterion) currently equates to 600, not

500, bears; (4) concerns that both ''and'' and ''or'' are used when referring to 500 bears and/or 48 females with cubs; (5) confusion as to why 3 consecutive years of non-compliance led to violation of the criterion in the supplement to the Recovery Plan, while only 2 consecutive years of non-compliance leads to violation of the criterion in the 2016 Conservation Strategy; (6) concerns that there are no mechanisms to prevent further decline if the population falls below 500; and (7) suggestions that the GYE population may not meet the 48 females with cubs-of-the-year requirement if bears respond to a stabilizing population through decreased reproduction and that the criterion should be less than 48 females with cubs. Both commenters and the States suggested that 500 bears was an arbitrary inflation of the minimum number suggested by Miller and Waits (2003) and may not be as conservative as proposed (Waples and Yokota 2007; Luikart *et al.* 2010). Additionally, the States requested we remove any reference to genetic fitness from criterion #1.

Response—In reference to criterion #1, 500 grizzly bears is not a population objective but a minimum population size to ensure short-term genetic health only. Further discussion about the biological basis for 500 individuals as a minimum population size is provided in the final demographic recovery criteria supplement to the Recovery Plan. All criteria are measured within the same demographic monitoring area. Criterion #1 specifies that both minimums of 500 bears and 48 females with cubs-of-the-year must be maintained, and that if the population size drops below either of those minimums in three consecutive years, the criterion will be violated. The Conservation Strategy, the Recovery Plan supplement, and this final rule have been edited for consistency, with all three documents now reading 'three consecutive years.'

If the population estimate falls below 500 in any year, the Service will conduct a status review to determine if re-listing may be warranted. The 2016 Conservation Strategy establishes a process through which corrections to population and habitat management can be made if any new scientific information or change in status arise that suggests the need to revise. The IGBST will conduct demographic reviews of the vital rates for the GYE grizzly bear population every 5 to 10 years and be able to detect if decreased reproduction occurred as a result of a stabilized population. Upon completion of a demographic review, the IGBST will provide the information to the YGCC, who will revise or amend the 2016 Conservation Strategy (2016 YES, p. 96) based on the best biological data and the best available science. Any such amendments will be subject to public review. In the 2007 revision to the Yellowstone demographic recovery criteria, YES advised the Service that maintaining a minimum population size of 500 individuals would be a conservative approach to ensure that the population stayed above the minimum of 400 bears recommended by Miller and Waits (2003, p. 4338) for genetic health.

Commenters suggested that Waples and Yokota (2007, entire) and Luikart *et al.* (2010, entire) support the idea that 500 bears may be conservative. However, those authors do not address the 50/500 rule but rather potential biases with estimates of effective population size (N_e) and how to address those biases. Please see Issue 96 for further discussion about the appropriateness of the 50/500 rule to ensure genetic fitness (in their entirety: Franklin 1980; Franklin *et al.* 2014) and current estimates of N_e (Kamath *et al.* 2015, entire) and the necessary minimum population size for genetic health. Although 48 females with cubs currently equates to 600 individuals, that number is dependent on the ratio of males to females in the population, which has varied in the past and is assessed by the IGBST as part of its demographic monitoring. We maintain in our discussion of criterion 1, in both this final rule and the revised demographic recovery criteria, that criterion 1 is not a population goal and that it refers to short-term genetic health (*i.e.,* genetic health over the next several generations (see *Demographic Recovery Criterion 1* under the *Recovery Planning and Implementation* section of this final rule).

Issue 18—Commenters also supplied feedback on criterion #2 including: (1) Confusion as to how the three consecutive 6-year sums are calculated and whether this would require 18 years before this criterion is assessed; (2) concerns that a 6-year sum of observations is a long time to wait to assess the criterion if female occupancy standards are not being met; (3) requests for clarification as to how occupancy is defined; and (4) suggestions that this criterion should apply to the whole DMA, not just the PCA.

Response—Clarifying language was added to criterion #2 in the final Recovery Plan supplement and this rule to demonstrate how three consecutive 6-year sums are measured (table 1). The running 6-year sum is designed to evaluate whether adequate dispersion of females exists most of the time, while allowing for an anomalous year where a unit might be unoccupied temporarily. Occupancy of a BMU is defined as the documented presence of females with young (all age classes of offspring), which is a conservative measure because the lack of confirmation of females with young from sightings in a particular BMU does not imply absence. Criterion #2 is measured based on the Recovery Zone (which equates to the PCA under a delisted scenario) because that area represents the core of the population where presence of females with young is an effective indicator to ascertain that reproductive females occupy the majority of the Recovery Zone and are not concentrated in a particular area of the ecosystem.

Issue 19—Commenters suggested that the standards in recovery criterion #3 were too low or too lenient, while others suggested it was too conservative and that the Service did not adequately justify the minimum numbers. Some public commenters and the States suggested that the criterion creates confusion on whether the population objective is 500, 600, 612, or 674. In addition, the States suggested the wording of the criterion creates confusion (1) that it could be interpreted as requiring the States to keep bears within a range of 612–735 bears; and (2) about the biological purpose of this 90% confidence interval. One commenter expressed confusion as to why the revised criterion now applies only to the DMA (as opposed to the entire DPS) and requested an explanation as to the potential consequences of the change. Another commenter requested clarification as to when and how the mortality rates in this criterion would be adjusted.

A number of commenters provided suggestions for how to change this criterion, including: (1) Making exceedance of mortality limits independent of a population minimum; (2) eliminating the 3-year wait between the population dropping below 612 and determining that the criterion is not met; (3) using an annual index of observed females with cubs-of-the-year to total observed mortality instead of proposed population measurement methods; (4) raising the average around which the population will be maintained (to be more precautionary); (5) halting discretionary mortality at populations of 674 bears, rather than 600 bears; (6) allowing the States more management flexibility for bear removal at populations below 600 (*i.e.,* not limiting these removals to ''human safety reasons''); (7) increasing the male mortality limit to account for the

decrease in females with cubs; and (8) eliminating the mortality limit for dependent young, since it is not currently being measured. State agencies also provided suggestions for changes to this last criteria, including: (1) Removing the explanatory paragraph on how background and discretionary mortality will be calculated and simply stating that annual mortality limits for independent females, independent males, and dependent young will be as shown in table 1 (table 2 of this final rule); (2) consistently stating whether mortality for independent females at population levels less than or equal to 674 bears would be less than 7.6 percent or less than or equal to 7.6 percent; and (3) removing mention of the requirement to halt discretionary mortality at populations less than 600 bears since this is the Tri-State MOA and does not belong in the recovery criteria.

Response—The objective of criterion #3 is to maintain the GYE grizzly bear population within the DMA around the average population estimate during the period of 2002 to 2014 as measured by the model-averaged Chao2 population estimator. Because populations naturally fluctuate through time (see figure 2), it is not reasonable to manage to an exact population target. The minimum population size for short-term genetic fitness did not increase from the 500 identified in criterion #1 as described in the 2007 delisting rule (72 FR 14866, March 29, 2007), our 2016 proposed delisting rule (81 FR 13174, March 11, 2016), and this final rule. The population objective in the 2007 delisting rule was to maintain a stable or increasing population within the GYE; the revised recovery criterion calls for maintaining the population around the average estimate from 2002 to 2014, a period during which natural stability was achieved.

We recognize the confusion created by the multiple numbers in criterion #3. In this final rule, the 2016 Conservation Strategy, and the revised demographic recovery criteria, we clarify that the criterion calls for maintaining the population within the DMA around the 2002 to 2014 model-averaged Chao2 population estimate (average = 674; 95% confidence interval (CI) = 600–747; 90% CI = 612–735). The lower bounds of the 90% and the 95% CIs are presented as the thresholds at which management changes would occur (*i.e.,* implementing a Biology and Monitoring Review and halting discretionary mortality except for ''human safety reasons,'' respectively). The demographic monitoring area is based on suitable habitat plus potential mortality sinks and was established to monitor mortality rates in the same area in which the population size is estimated. The suitable habitat contained within the DMA is sufficiently large to support a long-term, viable population such that mortalities outside of the DMA can be excluded from consideration.

Some have criticized the population objectives in the Conservation Strategy and proposed rule because the States could in theory manage below the long-term model-averaged Chao2 estimate from 2002 to 2014 of 674 bears. Importantly, this criticism misses the intent of criterion #3 as outlined in the 2016 Conservation Strategy and in the Recovery Plan Supplement (USFWS 2017, p. 5). The long-term model-averaged Chao2 estimate, 674 bears, is not a minimum recovery threshold. Rather, this number represents a population level that is at or near carrying capacity (van Manen *et al.* 2016, entire). Under the Act, species recovery is considered to be the return of a species to the point where it is no longer threatened or endangered. Recovery under the Act does not require restoring a species to carrying capacity, historic levels, or even maximizing density, distribution, or genetic diversity. While the goal of the 2016 Conservation Strategy and recovery criterion #3 is to maintain the population around this long-term average population target of 674 bears, a population below this number does not mean recovery has not been achieved. By attempting to manage within the 95 percent confidence interval (600–747) in accordance with criterion #3, the confidence interval provides a sufficient buffer to ensure that recovery is achieved, while also acknowledging that populations fluctuate naturally and it is not reasonable to manage to an exact population target.

The adjustable mortality limits set forth in table 2 provide a mechanism for maintaining the population within this confidence interval and serve as a buffer to ensure the population does not drop and remain below the lower bound of 600 bears. For example, a population estimate of fewer than 674 would trigger mortality limits of less than 7.6 percent for independent females. The best available science indicates that this population will increase in size at a mortality limit of less than 7.6 percent. Thus, if the population is estimated to be fewer than 600 bears, there would be no discretionary mortality, likely producing a total mortality rate less than 7.6 percent, which means the population would increase in size and return to the 95 percent confidence interval (600–747).

The Service recognizes it is at least theoretically possible that, even with a mortality limit of 7.6 percent, a population could drop below 600 bears for a certain amount of time while the population is increasing in size; however, we do not anticipate that it will remain below 600 bears for an extended length of time during this rebuilding period because of the other mechanisms (*e.g.,* Management Framework in table 3, additional safety margins listed below). The Service believes this is consistent with the recovery criterion. In addition, if the population falls below 612 individuals and the mortality limits are exceeded for three consecutive years, IGBST will conduct a Biology and Monitoring Review to inform the appropriate management response. And if the population drops below 600, all discretionary mortality will be halted, except as necessary for human safety. Additionally, if the limit is exceeded in any year, discretionary mortality the following year would be reduced by the number of mortalities that exceeded the limit. Non-discretionary mortality (*e.g.,* natural causes, vehicle strikes) varies from year to year, and we expect that there may be years when non-discretionary mortality alone reaches the limits based on population size, and there would be no discretionary mortality allowed. Reduced discretionary mortality would reduce the ability of the States to manage the grizzly bear population, and, therefore, we believe that the States have a strong incentive to manage above 600 bears.

Further buffering our recovery criteria is the fact that the Service and the States agreed on a counting methodology, the model-averaged Chao2 estimate, that is conservative, *i.e.,* it undercounts the number of bears. Schwartz *et al.* (2008, figure 5) concluded that at the model-averaged Chao2 estimate of approximately 700 bears, there are likely 350 other bears that remain uncounted. In other words, a Chao2 model-averaged estimate of 700 bears means that there are approximately 1,050 bears. As with Northern Rocky Mountain wolves, the Service is taking a conservative approach to counting bears to ensure bears remain recovered.

We provided additional safety margins to assure that the recovery criteria will be met. Four scenarios could lead us to initiate a status review and analysis of threats to determine if re-listing is warranted including: (1) If there are any changes in Federal, State, or Tribal laws, rules, regulations, or management plans that depart

significantly from the specifics of population or habitat management detailed in this final rule or the 2016 Conservation Strategy that would significantly increase the threat to the GYE grizzly bear population; or (2) a total population estimate is less than 500 inside the DMA in any year using the model-averaged Chao2 population estimator, or counts of females with cubs-of-the-year fall below 48 for 3 consecutive years; or (3) if fewer than 16 of 18 bear management units are occupied by females with young for 3 consecutive 6-year sums of observations; and/or (4) if the Service determines a petition to re-list from an individual or organization is substantial.

The Service has reviewed and revised the GYE grizzly bear demographic recovery criteria to ensure they are adequate under the requirements of the Act and that they have been fully achieved, and determined that a population at or above 600 individuals, by managing for a safety margin of 674 bears, together with criterions #1 and 2, is biologically recovered. States have committed to maintain the GYE population to within these goals. Collectively, these commitments indicate that the entire GYE population is likely to remain recovered.

Although there were many suggestions of slight modifications to this criterion, peer reviewers were supportive that this recovery criterion was scientifically sound and would maintain a recovered grizzly bear population. The mortality limit for dependent young is based only on human-caused mortality, which is what is currently measured and reported in the IGBST Annual Reports. The 2016 Conservation Strategy, this final rule, and the supplement to the Recovery Plan now consistently reflect each other and the Tri-State MOA: At population levels less than or equal to 674, independent female mortality would be less than 7.6 percent.

We disagree with comments that request we remove mention of the agreement to halt discretionary mortality at populations less than 600 bears because listing actions (including this final rule) are required to describe threats and the measures that address those threats. Discretionary mortality is a potential threat to grizzly bears, and we must explain how that threat has been addressed in this final rule. The main threat of human-caused mortality has been addressed through carefully monitored and controlled total mortality limits established in the Grizzly Bear Recovery Plan and incorporated into the 2016 Conservation Strategy (YES 2016a, pp. 33–53) and into State regulations as per tables 2 and 3 and *Factors B and C Combined* in this rule. The Tri-State MOA is not a replacement for our threats evaluation in this final rule.

Issue 20—We received comments from peer reviewers and the public that expressed confusion about the population management objectives and their scientific basis. Some commenters and peer reviewers suggested that it is unrealistic to manage the population to a single number when the confidence intervals are large and do not account for all sources of variation; moreover, commenters suggested that managing to a single number could jeopardize connectivity to other populations. The States requested removal of any language that indicates a population objective of exactly 674 bears and instead suggested language that implies managing for a population around the average of 674 bears or between the bounds of the 95 percent confidence intervals. Some commenters believed that the population objective should instead be a ''stable'' or ''increasing'' population, which would allow the population to continue to expand into currently unoccupied lands within the DMA; they requested that all documents contain an explicit reference to ''stability'' as the population objective. However, a few commenters expressed concerns with an explicit goal of managing for stability including: (1) that managing for stability is contrary to the Act's provisions; (2) that managing for stability could become challenging if the GYE's carrying capacity were to ever decrease (*i.e.,* additional habitat would need to be provided to allow for a stable population in this circumstance); and (3) that the objective of stability could allow mortality that is high enough to preclude opportunities to grow and expand the population of grizzly bears into other ecosystems. The States suggested that the Service remove all references to ''stability'' and instead ''refer to growth rate, reaching apparent carrying capacity, and population fluctuation.''

One peer reviewer recommended that the population goals be periodically reevaluated to allow for consideration of natural and anthropogenic changes in the ecosystem. Another commenter suggested starting with a very protective management objective that can be made more liberal if State management proves to be effective.

Response—The Service and our partners have all agreed to maintain the total population size around the average population estimate achieved during 2002 to 2014, otherwise known as the ''period of stability'' (YES 2016a, p. 35; YES 2016b, Appendix O). This recovery criterion was selected because: It represents a population level that is sufficiently robust to provide for the viability of the species; and it represents a period where the ecosystem was likely at or near long-term carrying capacity. As measured by the model-averaged Chao2 population estimator, this equated to 674 grizzly bears with a 95% confidence interval of 600 to 747. However, we agree that it is not practical or even possible to manage for an exact population target as populations naturally and inevitably fluctuate through time. The States' agreement to manage within the confidence intervals around 674 bears provides reasonable management flexibility in recognition of the complexities of the system and of managing grizzly bears.

The Service and the States understand that the actual population will vary around 674, and that mortality will be managed to ensure that the population does not drop and remain below 600. In our best professional judgement, management within this range will maintain recovery, as required by the Act, and a large, robust, healthy and viable population. We further conclude that the ecosystem can and will continue to support such populations. Put another way, habitat quality and management (discussed further under *Factors A and D*) provide us with sufficient assurance that habitat is unlikely to be the limiting factor in determining whether these targets are met now or within the foreseeable future.

With this as the backdrop, we set human-caused mortality limits that the best scientific and commercial information available indicated would help maintain the population around the 2002–2014 average. With more liberal mortality rates above 674, and more restrictive mortality rates below that, the population should fluctuate around that average. We anticipate that managers will further limit mortality the closer they get to 600 grizzly bears, as measured by the model-averaged Chao2 population estimator, at which point all discretionary mortality would be halted except as necessary for human safety. For further discussion, see Issue 19.

While some expressed concern that managing for stability may preclude population expansion and connectivity with other ecosystems, the State of Montana has indicated that they will manage discretionary mortality in the area between the GYE and the NCDE to maintain the opportunity for natural movement between the ecosystems (MFWP 2013, p. 9). Please see Issues 50

and 53 for further discussions on connectivity.

We recognize that some parties support continued population growth in perpetuity. We conclude that this is impractical, that the system has biological limits, that the average population estimate for the period of stability likely approximates or approaches those limits, that expansion into unsuitable habitat is largely unsustainable, and that continued population growth goes beyond the requirements of the Act for delisting. That is, the population no longer meets the definition of threatened or endangered even without population growth in perpetuity.

Issue 21—Many commenters expressed concern about the States' ''management objective for the DMA of at least a range between 600 and 747 (based on the 95% confidence interval of the estimated average population size between 2002 and 2014) and upon mortality rates to keep the population within this range,'' compared to the Service's reference to a management objective of a stable population around 674 bears within the DMA. Many commenters interpreted State management objectives as retracting ''any commitment to manage for a stable population of 674 bears'' and as intentions to reduce the population to only 500 or 600 bears, regardless of the method used to estimate the population size; conversely, the State agencies requested the Service emphasize in its final rule that the Tri-State management objective of managing for ''at least a range between 600 and 747'' in the DMA is ''at levels well above the population recovery criterion'' of 500 bears in the entire DPS. The States also requested that the final rule ''identify the States' agreed upon management objectives in relation to the recovery criteria.'' A peer reviewer noted that instead of ''establish[ing] population targets and associated specific harvest criteria,'' the States only identified a minimum population size for the total GYE grizzly bear population; the peer reviewer was concerned this oversight could lead to ''overharvest'' and that ''a lag in management response could drive the population below the desired minimum.''

Response—The Act requires the Service to ensure that all threats to the species have been removed or sufficiently ameliorated such that the species no longer meets the definition of threatened or endangered; meeting or exceeding established recovery criteria assists the Service in determining that the species may no longer need the Act's protection. Specific to the demographic recovery criterion 3 (USFWS 2017, p. 5), the States have made a number of clearly articulated commitments through the 2016 Conservation Strategy and Tri-State MOA to maintain a recovered bear population as measured by the established demographic recovery criteria. For example, in the Tri-State MOA (Wyoming Game and Fish Commission *et al.* 2016, pp. 4, 2.a.i.), the States have agreed to manage the GYE grizzly bear population within the DMA, to *at least* within the 95% confidence intervals associated with the 2002 to 2014 long-term average grizzly bear population estimate calculated using the model-averaged Chao2 estimator (*i.e.,* 600 to 747). This commitment does not preclude the States from managing above this recovery criterion using the best available science and current population information. Agreed-upon mortality thresholds, as described in the 2016 Conservation Strategy and criterion 3 in the Recovery Plan Supplement, ensure this commitment will be realized because those threshold limits are self-regulating. At higher population levels (*e.g.,* greater than 747), higher allowed mortality could cause the population to decline. However, once the population dropped below 747, a lower (more conservative) mortality rate would apply. If the population continued to drop and fell below 674, then a mortality rate would be reduced again, to a level that should result in an increasing population, as portrayed in table 2 in the rule.

At any population level below 674, mortality limits would be low, and thus, hunting or other discretionary mortality would be managed within these limits. In addition, all discretionary mortality would be halted if the population within the DMA dropped to 600, except as necessary for human safety. This increases the likelihood of maintaining a stable population around 674 bears. See Issues 19 and 66 for more information.

Issue 22—We received comments both supporting and objecting to our conclusion that the grizzly bear is biologically recovered. Some public and State commenters agreed that the GYE grizzly bear population is recovered because density-dependent factors are most influential in current population demographics, the population has consistently met the recovery criteria in recent years, and threats have been sufficiently ameliorated.

Conversely, other commenters presented reasons for disagreeing with our conclusions regarding recovery, including: (1) Confusion regarding our definition of ''recovered'' and our determination of how the GYE population has met demographic recovery criteria; (2) suggestions that higher grizzly bear numbers (ranging from 700–5,000 bears) are more indicative of a stable, recovered GYE population and that a metapopulation in the lower 48 States of 2,500–5,000 bears is necessary before recovery is achieved; (3) determination of recovery should consider age and sex structure, in addition to the number of bears; (4) concern that grizzly bears currently inhabit less than two percent of their historical range and that populations are less than three percent of their historical abundance; thus, we must further expand their range, connect to other healthy grizzly bear populations, and conduct additional reintroductions/reestablishment of populations before we can declare recovery; (5) the GYE population still meets the criteria to be listed as ''vulnerable'' by the IUCN Red List, and thus cannot be considered recovered; and (6) assertions, based on mortality rates exceeding mortality limits and the need to transplant bears, that threats have not been adequately addressed. In addition, some commenters suggested that recovery will not be achieved until carrying capacity is met, while one State suggested that carrying capacity is not a proper metric for assessing recovery.

Response—The Service has determined that the GYE grizzly bear population has increased in size and more than tripled its occupied range since being listed as threatened under the Act in 1975 and that threats to the population are sufficiently minimized. The participating States of Idaho, Montana, and Wyoming and Federal agencies have adopted the necessary post-delisting management objectives, which adequately ensure that the GYE population of grizzly bears remains recovered in the foreseeable future. The Service concludes, based on the best available scientific and commercial data, that the GYE population of grizzly bears is recovered and no longer meets the definition of a threatened or endangered species under the Act. While grizzly bears currently occupy only a fraction of historical habitat in the lower 48 States, the Service concludes that restoration of grizzly bears to all historical habitats (particularly those no longer capable of supporting grizzly bear populations) within the DPS boundaries or within the lower 48 States is not necessary or possible. The information presented in this rule supports the conclusion that the GYE grizzly bear population has

recovered and no longer meets the definition of endangered or threatened under the Act.

Although grizzly bears historically occurred throughout the area of the proposed GYE grizzly bear DPS (Stebler 1972, pp. 297–298), many of these habitats are not, today, biologically suitable for grizzly bears because of land conversion and a lack of natural food sources (*i.e.,* bison). For further information, please refer to our discussion of Suitable Habitat. Grizzly bear recovery in these areas of the species' historical range (unsuitable habitat) is unnecessary, because there is more than enough suitable habitat (*e.g.,* mainly public lands containing abundant natural food sources) to support a recovered grizzly bear population without grizzly bear occupancy of all historical habitat within the DPS boundaries. Therefore, additional recovery efforts in these areas are beyond what the Act requires.

We disagree with the suggestion that there must be 2,500 to 5,000 grizzly bears throughout the lower 48 States for recovery to be achieved in the GYE, and the United States District Court, District of Montana agreed with us, stating ''it would be nonsensical to require the Service to consider the grizzly bears' historic range throughout the United States as significant in relation to the Yellowstone grizzly bear'' if the GYE DPS does not remain threatened by these historical losses within its own boundaries (*Greater Yellowstone Coalition* v. *Servheen, et al.,* 672 F.Supp.2d 1105, 1125 (D. Mont. 2009), *aff'd on other grounds, Greater Yellowstone Coalition* v. *Servheen, et al.,* 665 F.3d 1015 (9th Cir. 2011) (the Montana District Court decision vacated the Service's 2007 delisting rule on other grounds). The fact that grizzly bears do not currently occupy all suitable habitat within the DPS boundaries does not threaten the population. To the contrary, it allows for ecological resiliency and population expansion in response to changing environmental conditions while maintaining consistency with the court's interpretation of the phrase, ''significant portion of its range'' (*Servheen,* 672 F.Supp.2d at 1125). Other issues such as habitat linkage are relevant to this rulemaking only to the extent that they affect the GYE DPS. For example, connectivity or a lack thereof, has the potential to affect this population's genetic fitness. As such, this issue is discussed and addressed in our five-factor analysis (see *Factor E,* above), in the 2016 Conservation Strategy, and in more detail in the response to Issue 96.

We measure the demographic recovery criteria as set out in the current revisions to the Recovery Plan, Demographic Recovery Criteria for the GYE (USFWS 2017, entire). The IGBST will conduct demographic reviews of the vital rates (including sex ratio and survival) for the GYE grizzly bear population every 5 to 10 years. Upon completion of a demographic review, the IGBST would provide the information to the YGCC who could then advise States and Federal land management partners if modifications to the 2016 Conservation Strategy are necessary. We disagree with the claim that we have focused only on demographic recovery. While demographic factors such as mortality control and population monitoring are critical to recovery, we have also established habitat-based recovery criteria to address habitat security (*i.e.,* motorized access), developed sites on public lands, and livestock allotments, while implementing extensive habitat monitoring programs for grizzly bear foods, human recreational use, and elk hunter numbers. Additionally, the IGBST annually monitors genetic diversity and trends in grizzly bear conflicts throughout the ecosystem. This comprehensive approach to recovery has led to reduced mortality, increased population numbers, and significant increases in range, and has allowed grizzly bears to reoccupy habitat they have been absent from for decades while ensuring demographic and habitat security into the foreseeable future, such that the species no longer meets the definition of a threatened or endangered species.

As previously stated, under section 4 of the Act, a species shall be delisted if it does not meet the definition of a threatened or endangered species, considering solely the best available scientific and commercial data. We may not adopt the conservation classification criteria of other agencies or organizations, such as the IUCN. However, we do evaluate and consider the underlying data other agencies or organizations have relied upon in making their own conservation classifications. While it is true the GYE grizzly bear population meets one of the IUCN criteria for vulnerable (population size estimated at less than 1,000 mature individuals), our recovery and post-delisting management goals were designed to provide for the long-term conservation of the GYE grizzly bear population by ensuring sufficient control of human-caused mortality and maintenance of suitable habitat.

Finally, regarding carrying capacity, this has never been one of our recovery criteria. While there are multiple lines of evidence suggesting the population is at or near carrying capacity (*e.g.,* decreased cub and yearling survival, increased generation interval, decreased home range size), we have not used this information to assess recovery. Instead, this information has helped us understand some of the more recent demographic changes the IGBST has documented, such as a lower population growth rate between 2002 and 2011 than that documented between 1982 and 2001. See Issue 37 for further discussion on carrying capacity.

Other Comments on Whether To Delist

Issue 23—Multiple commenters believed our description of the taxonomy of grizzly bears in the GYE is no longer the best available science. They presented that the GYE grizzly bears are ''part of a clade (Clade 4) with an ancient and unique history, a restricted distribution, and warranting consideration as evolutionarily unique and threatened genetic linkage.'' They asserted that because this unique taxonomic classification includes, and is limited to, the entire lower 48 grizzly bear metapopulation, recovery must address grizzly bears in the entire lower 48 States as a whole unit, instead of splitting out the GYE.

Response—The Act allows consideration for listing, reclassification, and delisting of species, subspecies, and DPSs. As part of the process to designate one or more units as a DPS, we evaluate their discreteness and significance to the taxon (61 FR 4722, February 7, 1996). While this analysis is often informed by genetics, we are not limited to large genetic units such as clades. After a comprehensive analysis in both our 2007 delisting determination (72 FR 14866, March 29, 2007) and an updated analysis in the proposed delisting rule (81 FR 13174, March 11, 2016), and after review of peer and public comments addressed in this final rule, we have determined that the GYE population of grizzly bears is discrete and significant, meeting the definition of a DPS under the Act (61 FR 4722, February 7, 1996). Therefore, the GYE grizzly bear is a listable entity under the Act, and may be considered and classified separately from other listable entities. Our recognition that the GYE grizzly bear population qualifies as a DPS and its separate listing or delisting is also consistent with the 1993 Recovery Plan's (which predates the Service's 1996 DPS policy) stated intention to delist each of the remaining populations as they achieve their recovery targets and an associated five-factor analysis under section 4 of the

Act indicates that they no longer meet the definition of a threatened or endangered species (USFWS 1993, p. ii).

There is disagreement among geneticists as to the conclusion that the genetic evidence suggests four different evolutionarily significant units (ESU) in North America (Waits *et al.* 1998, p. 414), with Clade IV representing brown bears in Southern Canada and the coterminous lower 48. Clades based on mitochondrial DNA may be evidence of a historical event but do not accurately reflect genetic divisions in current populations as gene flow is disproportionately affected by males as a result of their larger movements (Paetkau *et al.* 1997, p. 1950).

In the event that a taxonomic change is eventually accepted as the best available science based on genetic differentiation between brown bears in North America (Waits *et al.* 1998, p. 414), the GYE population's discreteness would be unchanged and the significance of this population relative to a smaller taxonomic unit would continue to meet the standards of the DPS policy (loss of GYE relative to this smaller unit would continue to represent a significant gap in the range of the taxon) (61 FR 4722, February 7, 1996). Furthermore, such a hypothetical finding would not alter the recovered status of this population.

Issue 24—We received comments both agreeing and disagreeing with our determination that the GYE grizzly bear should be delisted. Those who supported delisting, including State commenters, suggested that: (1) States would allocate more money towards grizzly bear conservation and management, post-delisting; (2) funds could be allocated to other at-risk species in greater need; (3) delisting was appropriate, even if future impacts to the population cannot be predicted with certainty because recovery criteria had been meet and the population was not at risk of declining; and (4) there are too many bears in the GYE, resulting in increased conflict with livestock and hunters, posing a safety issue, and potentially causing eventual collapse of the entire ecosystem.

Conversely, other commenters asserted that delisting: (1) Was premature because we based it primarily on population size or ''social carrying capacity,'' or on insufficient time to measure success, public input, and inadequate or unreliable data; (2) contradicts the precautionary approach to wildlife management mandated under the Act, especially considering potential threats from climate change, implementation of hunting, and the low reproductive rates of bears; (3) contradicts opinions of grizzly bear biologists cited in an Ohio State University study; and (4) could lead to population declines or extinction of the GYE grizzly bear. Other commenters suggested that Federal protections be increased, rather than removed, while another suggested that excess bears should be culled rather than be delisted. Some commenters asserted that the goal of the Act is to recover a species, not delist it: We should ensure that re-listing will not be necessary in the foreseeable future, rather than delisting as soon as a population meets minimum goals.

Many commenters recommended delaying delisting until we can demonstrate successful reproduction outside of National Parks and effective dispersal and connection between grizzly populations.

Some commenters opposed delisting because they suggested that management would revert to the States and hunting would likely follow, with bears classified as predators and then shot, poisoned, or killed on sight. One commenter thought that proposed State replacements for section 7 consultations, section 9 take prohibitions, and an ability to bring legal challenge against management actions were inadequate. Another commenter asserted that, after the 2007 delisting, GYE grizzly bears were placed back on the List of Endangered and Threatened Wildlife because we failed to protect the species. One commenter suggested delisting could not be justified given the intrinsic values of the species.

Response—The principal goal of the Act is to return listed species to a point at which protection under the Act is no longer required (50 CFR 424.11(d)(2)). A species may be delisted on the basis of recovery only if the best scientific and commercial data available indicate that it is no longer endangered or threatened within all or a significant portion of its range (50 CFR 424.11(d)). As described later in this rule, we determine that, based on the best available data, the GYE DPS meets neither of these definitions for listing, thereby justifying delisting due to recovery.

To be clear, the Act does not contain a mandate or requirement that we institute a ''precautionary approach to wildlife management.'' Instead, the Act mandates that we make decisions about conservation status based on the best available scientific and commercial data, which informs the Act's definitions of threatened and endangered species. We remain confident that this population has long been recovered and will remain so after delisting.

Furthermore, this final rule, the 2016 Conservation Strategy, and the protective measures in Montana, Wyoming, and Idaho implement a conservative management approach by establishing science-based population criteria tied to the demographic recovery criteria, while also maintaining distributional recovery criteria. In addition, the adaptive management system in the 2016 Conservation Strategy incorporates the results from intensive monitoring of population vital rates, habitat standards, and major foods into management decisions and ensures the GYE grizzly bear DPS will remain recovered under the management frameworks now in place in Wyoming, Idaho, and Montana. In short, the regulatory frameworks now in place give us great confidence that this success story for American conservation and the Act will be maintained and that future generations will be able to see and enjoy grizzly bears in the GYE.

Strict regulations and regulatory mechanisms within State statute or codified regulation are in place to protect grizzly bears within the DPS boundaries. The States of Wyoming, Montana, and Idaho have classified grizzly bears throughout the entire GYE DPS boundaries as a game animal and have never suggested they will be classified as predators (W.S. 23–1–101(a)(xii)(A); W.S. 23–3–102(a); MCA 87–2–101(4); MCA 87–1–301; MCA 87–1–304; MCA 87–5–302; IC 36–2–1; IDAPA 13.01.06.100.01(e); IC 36–1101(a)). Game animal status is much more protective than predator status. Any grizzly bear found outside of the DPS boundaries would be protected under the Act as a threatened species. If any of the three States decided to classify grizzly bears as predators (an outcome that has not been proposed or even discussed to our knowledge), we would consider this a significant departure from current State laws and regulations and we would immediately initiate a status review.

Lastly, while we respect the moral and ethical reasons some members of the public may have for disapproving of this decision, delisting is the appropriate decision based on the current status of the DPS and the statutory requirements of the Act.

Issue 25—One commenter claimed we inappropriately conclude that threats become irrelevant when they ''can be managed.'' This commenter suggested that threats we and others successfully manage (such as genetic health) should still be regarded as a threat during our evaluation.

Response—In our five-factor analysis of threats to the GYE population of grizzly bears, we do not claim that managed stressors are irrelevant but rather that these threats have been eliminated or sufficiently ameliorated such that the DPS no longer meets the definition of a threatened or endangered species. We considered all of the factors under section 4(a)(1) of Act and assessed the cumulative effect that any threats identified within the factors—as ameliorated by any existing regulatory mechanisms or conservation efforts—will have on the GYE grizzly bear population now and in the foreseeable future. Based on our analysis, we have determined that the GYE grizzly bear population no longer requires the Act's protection. Please see the *Determination* section at the end of the threats analysis for more information.

Issue 26—Some commenters expressed skepticism towards our data, analysis, and cited research. Commenters claimed that our rule was not based on the best available science because: It is contrary to Dr. David Mattson's ideas; NPS leaders have questioned our analysis and conclusions; much of the published research we cited in our proposed rule was not adequately reviewed, thus this research is not reliable because it is still undergoing ''post-publication'' scrutiny; our process has seemed ''convoluted''; and an email from the Service's former Director released under the Freedom of Information Act (FOIA) contained the phrase ''this recommendation seem[s] at odds with the best available science standard of the ESA.'' Commenters opined that the raw data used in our analysis was not made available for independent review, even though it belongs to the public since taxpayers paid for the research. They expressed concern that the ''monopoly'' the IGBST has on grizzly bear population data prompts groupthink and a general lack of transparency. One commenter requested we ''establish a review panel of independent, academically qualified scientists who are not involved in current grizzly bear research in the GYE.'' Another commenter claimed that the peer review process does not sufficiently detect error or bias and that it is no more likely to detect error or bias than by random chance. The same commenter took issue with the proposed rule's reliance on models because there is never one correct model, claiming that model building is ''the most bias-prone form of analysis.'' Another commenter cautioned against committing Type II errors in analysis (a ''false negative'').

Response—The Act requires us to make our listing determinations based upon the best scientific and commercial data available. In this case, we relied upon numerous peer-reviewed and published documents that were readily available either through regulations.gov in this rulemaking's docket, at *http://www.fws/gov/mountain-prairie/es/grizzlybear.php,* or by appointment with the Service's Grizzly Bear Recovery Coordinator. This information was publicly available when we published our proposed rule and during our public comment period. For example, mortality information, including date of death, sex, age, certainty of death, if the bear was marked or not, and drainage location, are published annually in the IGBST's annual reports, available at *https://www.usgs.gov/centers/norock/science/igbst-annual-reports?qt-science_center_objects=1#qt-science_center_objects.* It is important to note that we did not rely upon any of these raw data to make our decisions, but rather on the peer-reviewed published interpretations of that raw data. We did not have any additional data than what was available to the public.

The IGBST approach to scientific studies involves extensive collaborations and contracts with independent academic and agency researchers who do not serve on the IGBST. Data used to calculate population size are available in the tables provided by Keating *et al.* (2002, p. 171), included in the Supplement to the Reassessing Methods Document (IGBST 2006, p. 7), as well as the annual reports produced by the IGBST. Estimates of sustainable mortality limits recommended in the Reassessing Methods Document are based on survival and associated population growth rates presented by Harris *et al.* (2006, p. 50). All results of Harris *et al.* (2006, p. 48) where estimates of population growth were made can be duplicated from data available in the other chapters of the Monograph. Data used to calculate transition probabilities are included in the Supplement to the Reassessing Methods Document (IGBST 2006, pp. 19–21). The IGBST also released the raw data files and digital records from 1975–1998 in response to a FOIA request. The IGBST replied to a later request for such data but has not yet received a formal FOIA request. We have released data that was in our possession and not otherwise prohibited from release by law (*i.e.,* exact locations of grizzly bears obtained via VHF or GPS telemetry (*i.e.,* ''raw data'') were not in our possession, and the Omnibus Parks and Public Lands Act of 1998 (16 U.S.C. 5937) exempts release of specific locations of threatened species within National Parks units).

As discussed under Issue 10, we have followed our peer review policies. Peer review is a widely accepted approach within the scientific community to maintain the highest standards of quality and provide credibility. It is designed to detect biases and flawed assumptions by allowing objective and anonymous reviewers, when appropriate and applicable, to examine the methods, results, interpretation, and conclusions of colleagues to identify weaknesses and suggest improvements before publication. Peer review provides a critical evaluation of the subject work by similarly qualified experts and constitutes a form of self-regulation by qualified members of a profession within the relevant field. In short, peer review is an integral part of the scientific process, and publication in a peer-reviewed journal is often a key consideration in our assessment of what constitutes best available science. The GYE grizzly bear population is the most studied in the world, and the peer-reviewed scientific journal articles used in the proposed and final rules represent the best available science.

Models are never perfect, but are crucial to the scientific process. Models can be reliable and informative as we consider the best scientific and commercial data available. Modeling typically requires a set of assumptions and can be prone to error, including Type II errors. Incorrect inputs or failure to account for certain variables or assumptions can result in inaccurate outputs and conclusions. By design, scientific peer review identifies and corrects potential concerns with modeling. Models used by IGBST and other scientists are based on commonly used and broadly accepted approaches in wildlife science. To suggest that models should not be used or relied upon is too generalized a conclusion and, in our view, unfounded. Not using scientific inference from modeling would reject the role of science. Ignoring available modeling could be directly counter to the Act's requirement that we base our decisions on the best available science.

We are aware of and considered ideas that are contrary to our conclusions, including those of Dr. David Mattson, who contends that the population is declining due to declining food sources, drought, invasive species, and habitat loss. However, the peer-reviewed research does not support this idea. Please see *Factor E: Changes in Food Resources* for further discussion.

Issue 27—Commenters expressed concerns with the methodology used in population viability modeling, model selection, and modeling timeframe. Commenters suggested that the Service is basing decisions on a modeling effort that failed to investigate the relationship between population and habitat data that used a 100-year modeling timeframe that was too short for a long-lived species, and that used an improper modeling endpoint. Commenters thought we used modeling to determine the timeframe required for the population to drop to zero rather than the timeframe that would result in an inadequate number of individuals to maintain the population. Commenters also requested clarity on specific model parameters we used in decision-making. These include the specific threshold used to determine extinction probability (*e.g.,* 5 percent risk of extinction), whether the model results were based on density-dependent or independent data, and whether we included habitat change data.

Response—The proposed rule (81 FR 13174, March 11, 2016) referenced key findings of a population viability analysis conducted by Boyce *et al.* (2001, entire), which represents the primary peer-reviewed source for this type of analysis for the GYE grizzly bear population. The details of the model parameters were provided in Boyce *et al.* (2001, p. 8), which should be consulted as the original literature source.

Opinions vary regarding what criteria should be evaluated (*i.e.,* population of zero versus some other threshold level), but the proposed rule used a commonly applied metric of population viability, the probability of extinction (or its reverse, probability of population persistence) over certain timeframes. A 100-year timeframe is commonly used for viability analyses of many species, including long-lived vertebrates. The final rule for delisting of the Louisiana black bear (81 FR 13174, March 11, 2016), for example, also referenced population viability analyses with the probability of persistence measured over a 100-year timeframe (Laufenberg and Clark 2014, p. 2). Moreover, the GYE proposed rule also refers to a 500-year timeframe for the GYE grizzly bear population.

The GYE proposed rule clearly cautioned the reader that the analyses of Boyce *et al.* (2001, p. 34) did not consider possible changes in vital rates due to habitat changes. Vital rates have indeed changed since the time of the analysis (although the preponderance of evidence indicates these changes in vital rates were associated with increased population density, rather than changes in food resources). The GYE proposed rule recognized that the outcome of the population viability analyses could change with different vital rates, but also emphasized that further research (Nielsen *et al.* 2006, p. 227; Schwartz *et al.* 2010, p. 665) indicated the key importance of secure habitat as an effective management tool to ensure population persistence.

Measurement of and Interpretation of Population Parameters Issues

Issue 28—We received comments from peer reviewers and the public that expressed concern about the use of the Chao2 estimate method to estimate the grizzly bear population size, asked for additional details, declared the Chao2 method ''outdated,'' and questioned whether the Chao2 method is the best available science, while the States supported our use of Chao2 and suggested it represents ''the best available science for monitoring and evaluation of population trends.'' Peer reviewers expressed confusion about what the Chao2 estimation methodology entails, including: (1) Questions as to whether the Chao2 estimator is an estimate of the total number of females with cubs or an estimate of overall grizzly bear abundance; and (2) requests for additional details on how model averaging is used with the Chao2 estimator, given the potential issues with model-averaging (Cade 1995). In addition, commenters suggested that we provide more details regarding the demographic inputs and how they are determined; the model assumptions; how the initial population size was estimated; how the sex-age class distributions were estimated; why the current ratio of 1 independent male to each independent female is used as opposed to the previous ratio of 0.635; how cumulative uncertainty in the population model inputs are carried over into final uncertainty of the estimated population size; how natural mortalities were estimated and included; and whether the population size is based on unique number of females with cubs or litter size. Peer reviewers asked if the Chao2 estimator was published in a single paper in its entirety or had been subject to peer review.

Commenters also cast doubt on the accuracy and reliability of the Chao2 population estimation method, especially considering the research of Doak and Cutler (2014a, 2014b). These concerns included: (1) Concerns that Chao2 becomes less accurate with time; (2) confusion about the wide range of estimated population sizes (according to Thuermer (2016), the number of bears, based on the Chao2 method, could range anywhere from 552 bears to 1,110 bears); (3) suggestions that 40 percent variance (the apparent variance associated with the Chao2 estimate) is unacceptable; and (4) suspicions about the fact that, in 2007, the population estimate jumped from the long-time estimate of 260–600 bears to 700 bears because delisting was under consideration. One commenter wondered how the raw counts and Chao2 estimates of females with cubs differ in Keating *et al.* (2002, table 5) and records from the mortality workshop for the years 1999 to 2001. Another commenter suggested that the Chao2 estimate is only conservative if the population is indeed increasing; this commenter noted that, if the vital rates and mortality rates are incorrectly estimated, then the population could decline undetected. On the other hand, one commenter worried that the Chao2 estimator was too conservative ''when the population is continuing to increase and expand beyond its biologically suitable and socially acceptable habitats.''

Several comments were concerned with the measurement and interpretation of unique females with cubs, and how potential biases in these counts could lead to overestimation of the Chao2 population estimate (which is based on counts of females with cubs). The first source of bias commenters cited stems from increased sightability; over time, as bears have increased their use of moth sites, which are easier to monitor, it has become easier to find and count individual bears. These commenters claimed that the increasing trend of the number of females with cubs in IGBST monitoring data could stem from the fact that it has become easier to count bears and not from the fact that there are actually more bears in the GYE. The second source of bias commenters cited relates to increased unreliability of unique sightings of females with cubs. Based on the guidelines for how the IGBST counts females with cubs, females sighted with differing numbers of cubs are considered unique (*e.g.,* a female spotted with two cubs near where a female with three cubs was also spotted is counted as an additional unique female). However, increased cub mortality increases the difficulty in distinguishing between unique females with cubs; between multiple survey flights, a female could lose a cub and thus be counted twice (once as a unique female when she has three cubs and again as a unique female when she is

spotted with only two cubs). This situation can again cause overestimation of the number of females with cubs. The third source of bias comes from increased search effort; variable efforts in surveys could lead to artificially higher counts of females with cubs. One commenter suggested that courts have ruled our use of a population estimator based on ''females with cubs'' illegal (*Funds for Animals* v. *Babbitt,* 903 F. Supp. 96, 114 (D.D.C. 1995)). Commenters asked that we discuss potential methods for managing these biases associated with counts of females with cubs (and thus with Chao2), such as specifying that population monitoring will continue indefinitely at the same intensity, the same distribution, and under the same design to account for potential biases from variable search effort and conditions.

Commenters raised concerns about other sources of bias in the Chao2 estimator. First, some commented that the population estimate is influenced and potentially biased by the multipliers used for dependent young, pre-reproductive independent females, and independent males, and by changing survival rates (*i.e.,* the increase in the population estimate as a result of the increased survival rate used for adult males after 2012). Second, commenters claimed that the Knight Rule (the rule we use for distinguishing unique females with cubs) could reduce the ability of Chao2 to detect changes in population size. Under these rules, we consider two females spotted within 30 km (19 mi) of each other as the same bear. As grizzly bear populations become denser, there will eventually be a maximum number of bears that surveyors can possibly count given these rules (*i.e.,* one bear in every 30 km (19 mi) radius); they referred to this maximum number of bears countable under the Knight Rule as the ''density threshold.'' One commenter worried that once the population exceeds this threshold, managers will not be able to detect declines in the population between the actual number of bears and this threshold, since the counts of bears will be artificially stagnant. Another commenter worried that managers could misinterpret reaching the density threshold as reaching the carrying capacity of the population. Commenters suggested that we should use the methods in Ordiz *et al.* (2007) instead of the Knight Rule. Third, one commenter suggested that the method is insensitive to rapidly changing conditions.

Response—The Chao2 estimate method is the best science that is currently available and that can apply under the current monitoring schemes. Whereas many other and newer estimation techniques exist, they do not necessarily provide the best available science for the desired monitoring objectives, as described below. Furthermore, the Chao2 technique is one of several that the IGBST uses to monitor population size and trend. Although there are other methods that would likely result in greater precision and lower bias (*e.g.,* DNA sampling), not only are they currently not available with the data we have, the annual implementation of these methods would be prohibitive both in costs and logistics. The IGBST estimated that the costs for a *single* DNA-based population estimate for the entire GYE would be approximately $11 million. The IGBST will continue to investigate cost-effective techniques that may result in relatively unbiased estimates with greater precision. We have provided clarifications in this final rule (see *Population and Demographic Recovery Criteria*) and the 2016 Conservation Strategy (see Chapter 2) to address comments concerning the application and transparency of the definition of the Chao2 estimator. The model-averaged Chao2 provides an estimate of the number of females with cubs-of-the-year, rather than an estimate of the overall grizzly bear abundance, which is then used to derive a total population estimate. In response to a comment about potential issues with model-averaging, our interpretation of Cade (2015, entire) and others (*e.g.,* Fieberg and Johnson 2015, entire) is that model-averaging of the regression coefficients is not recommended, but that model-averaging of predictions (*i.e.,* in this instance, annual estimates of the number of females with cubs-of-the-year based on a linear and quadratic model) is appropriate. Thus, the term ''model-averaged Chao2 estimate'' is appropriate and should be continued.

We have provided clarifications in the final rule (see *Population and Demographic Recovery Criteria*) and the 2016 Conservation Strategy (YES 2016a, pp. 33–53) to address comments concerning the transparency of the definition of the Chao2 estimator. Although the details of the Chao2 estimator are not published in their entirety in a single article, we have expanded the description of the Chao2 estimator to include all relevant peer-reviewed literature. All of the details are provided in the literature regarding the application of the Chao2 estimator and the inputs and would be too technical and cumbersome to include in the final rule and 2016 Conservation Strategy, which were revised to provide all relevant references for the Chao2 estimate technique.

The derivation of total population size introduces additional uncertainty into the total population estimate, but we have no data that suggest that bias would increase. Indeed, the vital rates (*i.e.,* survival and fecundity) derived from the IGBST's large sample of radio-marked bears monitored annually, which form the basis for the multipliers, have been published in multiple peer-reviewed papers using well-established techniques (*e.g.,* in their entirety: Schwartz *et al.* 2006b; van Manen *et al.* 2016). The most recent analyses by van Manen *et al.* (2016, p. 305) showed that male survival rates increased from 1983–2001 to 2002–2012.

The survival estimates are not inflated and, in fact, may be underestimates because IGBST assigns the month of death as the last month an individual bear was known to be active when a bear was lost from monitoring and the date of death was unknown. If some of these individuals were lost the following month, the overall estimate of survival would be higher (Haroldson *et al.* 2006, p. 40). Regarding insensitivity to rapidly changing conditions, IGBST is currently investigating the power of the current population estimation protocol to detect a declining trend (see Issue 29). One commenter referred to the findings of the demographic review conducted by IGBST in 2011, which was triggered by the monitoring system indicating a change in population trend had occurred. That demographic review was based on 2002–2011 data and indicated that population growth had slowed starting in the early 2000s and, importantly, also indicated that several vital rates had changed (*e.g.,* lower survival of cubs and yearlings, greater survival of independent males). Because IGBST uses vital rates to extrapolate population estimates of females with cubs-of-the-year to a total population estimate, the relative proportions of different population segments changed. Due to the increase in survival of independent males, the sex ratio of independent males and females is now 1:1, rather than the previous ratio of 0.635, which means the independent male segment in the population is now proportionally greater than what was documented in 1983–2001.

Thus, while population growth indeed slowed down, a given estimate of the number of females with cubs-of-the-year based on 2002–2011 vital rates translates into a larger total population compared to 1983–2001 data because of the greater proportion of independent males in the population. These observations are not an indicator of the

''high uncertainty in the monitoring of this population.'' In fact, the IGBST concluded that the monitoring system was effective: (1) The IGBST developed a population monitoring system and established triggers that indicate when a change has occurred; (2) the IGBST noted when a change in population growth was detected; (3) the IGBST studied the demographic factors (*i.e.,* vital rates) associated with that change (*e.g.,* lower cub and yearling survival, greater independent male survival; slight reduction in fecundity); (4) the IGBST tested hypotheses regarding these changes in vital rates (effects of change in food resources versus density dependence); and (5) the findings were published in peer-reviewed journals and other outlets so that managers can adjust management accordingly. The biases associated with the Chao2 method and how they are carried through were identified in IGBST (2012, p. 20). The population size is based on the unique number of females with cubs-of-the-year; litter size is only a factor in separating unique females with cubs.

In response to doubts on the accuracy and reliability of the Chao2 population estimation method: (1) We acknowledge an underestimation bias in Chao2 that increases as the population grows (*i.e.,* underestimation is greater as the number of females with cubs in the population increases); however, this bias translates into a conservative approach to management of the GYE population. (2) We also acknowledge that other methods yield higher population estimates (*e.g.,* Thuermer 2016, entire); however, the higher population estimates mentioned by Thuermer (2016, entire) were based on the Mark-Resight technique, which also yields low precision when utilized for trend detection. (3) Keating *et al.* (2002, pp. 172–172) discusses the coefficient of variation associated with the Chao2 method. (4) In 2007, the IGBST implemented the model-averaging technique, which resulted in a slight increase in population estimates. The IGBST decided not to apply this technique retroactively to population estimates in years prior to 2007. In addition, population estimates increased with increasing male survival, which resulted in more males in the estimated population (IGBST 2012, p. 33). These decisions were made independently by the IGBST and had no connection with the delisting under consideration. The raw counts and Chao2 estimates of females with cubs differed in Keating *et al.* (2002, p. 166) because they used only females with cubs seen without the aid of telemetry in the Yellowstone Recovery Zone plus the 10-mile perimeter, whereas the IGBST (2006, p. 5) assessment included females throughout the GYE. It is possible that the population is growing and expanding beyond the DMA while the Chao2 method is showing a stable population because the population is only estimated for within the DMA and the Chao2 technique results in a conservative estimate and the underestimation bias increases with population size.

Schwartz *et al.* (2008, entire) demonstrated that the bias associated with the measurement and interpretation of unique females with cubs-of-the-year results in an underestimation of the population estimate, with increasing negative bias as the number of females with cubs in the population increases. Doak and Cutler (2014a, entire) critiqued the approach taken by the IGBST of using the model-averaged Chao2 estimator of females with cubs-of-the-year to derive the total population estimate. They claim that increases in grizzly bear population estimates from 1983 to 2001 can be attributed to factors other than actual increases in population size, primarily observation effort and sightability of female grizzly bears with cubs-of-the-year. However, in a rebuttal, van Manen *et al.* (2014, entire) demonstrated that the simulations of Doak and Cutler (2014a, entire) were not reflective of the true observation process nor did their results provide statistical support for their own conclusions. In addition, van Manen *et al.* (2014, pp. 326–328) found that there was no justification to account for ''bias associated with the method or disagreements in the scientific community about the population estimate of ~700''; particularly given the demonstrated underestimation bias of the rule set (Schwartz *et al.* 2008, entire) and the Chao2 estimator (Cherry *et al.* 2007, entire). Both sources of known negative bias contribute to conservative population estimates. The related comment disregards the notion of the central tendency of data and mischaracterizes the scientific concept of uncertainty. We answer this using a relevant quote from Schwartz *et al.* (2006b, p. 62), who addressed the issue of uncertainty in demographic estimates as they relate to management: ''Thus, we see no escape from uncertainty. To claim that no decision about what has occurred should be adopted until uncertainty is removed or to claim that the only acceptable decision adopts some lower confidence limit as truth is to reject the role of science. If the possibility of population decline is treated as the fact of population decline (even where overwhelming evidence suggests otherwise), there is no need to spend money on research or monitoring because the management approach would be identical regardless of what data were produced. Because it is impossible to absolutely reject the hypothesis of decline, one would always manage as though a decline had occurred. To us this would seem poor policy.''

The critique of increased search effort and sightability were addressed in substantial detail in the response by van Manen *et al.* (2014, pp. 324–325) to the critique article by Doak and Cutler (2014a, entire). Specifically, in figure 1 of the Supplemental file from van Manen *et al.* (2014), they demonstrated that the number of flight hours increased as flight observation areas were added to accommodate range expansion from 1986–2010. The correlation coefficient suggested this was a near 1-to-1 relationship. One key aspect of the Chao2 estimator is that it reduces bias due to variation in sightability among different females with cubs-of-the-year. Additionally, model averaging smooths annual variations in counts that are due to both sampling and process variation, with the process variation coming from the proportion of females that have cubs at the side in any particular year. If anything, changes in litter size would increase underestimation bias and thus be conservative. Moreover, while cub mortality has increased, the geographic distribution of observed litter size has not.

The suggestion that we continue the current method of population monitoring indefinitely, including intensity, distribution, and design, is addressed in this final rule (see *Population and Demographic Recovery Criteria*) and in the 2016 Conservation Strategy (YES 2016a, pp. 33–53). In response to the suggestion that we review Ordiz *et al.* (2007, entire) as an alternative to the Knight rule, there are multiple techniques and different rule sets that can be developed to estimate unique females with cubs-of-the-year. The Ordiz *et al.* (2007, entire) paper does not describe a rule set but examines relationships among distances and number of days of individual females with cubs-of-the-year; data on litter size were not incorporated. Schwartz *et al.* (2008, entire) investigated similar distance and time relationships for GYE female grizzly bears with cubs-of-the-year, but no adjustments to Knight *et al.* (1995) were made to reduce the probability of Type

I errors (*i.e.,* mistakenly identifying sightings of the same family as different families). The IGBST may consider alternatives to the existing rule set in the future; if those alternatives are deemed to improve the best available science, new procedures will be adopted per the process outlined in this final rule and the 2016 Conservation Strategy. Although it is true that changes in the estimates of females with cubs-of-the-year may be more difficult to detect once above a density threshold, this is again a conservative approach. The analogy is a thermometer that does not register temperatures above 102 degrees; as long as the value of interest is below 102, it registers only when it drops to that point.

The rule set used in the Chao2 estimate for identifying unique females with cubs-of-the-year is conservative and becomes increasingly conservative with greater numbers of unique females with cubs-of-the-year (*i.e.,* population level determines the level of bias, not population growth). Although the Chao2 estimate does become increasingly negatively biased with increasing density, the IGBST uses additional data for demographic inference (*i.e.,* to determine the population trend and if the population is reaching carrying capacity). Please see Issue 29 for further discussion on population trend. Combined with recent analyses (van Manen *et al.* 2016, entire), these data suggest that density-dependent factors may be operating and are an indicator of the population at or near carrying capacity. Lastly, efforts are currently under way by the IGBST to: (1) Address the underestimation bias of Chao2, and (2) examine the ability of the Chao2 technique to detect a change in population trend over time. However, given the detailed discussion above, the Chao2 method remains the best available data upon which to answer the question at hand.

Issue 29—Commenters expressed concern about how population trend is measured, including: (1) A desire for justification for the use of linear and quadratic models; (2) that we should not use observations of females with cubs to estimate population trend because this measure is unreliable at high population densities; (3) confusion as to whether we use number of unique females with cubs or litter size to estimate population growth; (4) that we should only use data since 2000 when estimating population trend since the smoothing approach employed in the Chao2 method is highly sensitive to the time period being modelled (and major changes occurred in the GYE in 2000); (5) that the population trend declines significantly to a 0.8 percent annual increase if modelers only use data from 2007 to the present; (6) that the IGBST methods overestimate the growth rate because they do not adequately account for senescence in birth and death rates of females (Doak and Cutler 2014a, 2014b); and (7) questions as to how cumulative uncertainty in the population models are carried over into final uncertainty of estimated population growth. Some commenters were concerned with a potential lag effect (*i.e.,* that the model-averaged approach is insensitive to rapidly changing conditions and that a negative population trend would not be detected until it is too late); Doak (1995) and McLellan (2015) have reported lag effects between habitat decline and population decline.

Several commenters suggested additional or alternative methods to apply in detecting the population trend including: (1) Comparing the annual uncertainty in the population estimates to long-term averages; and (2) using capture-recapture data to estimate population trend rather than the trapping effort data used by van Manen *et al.* (2016) and Bjornlie *et al.* (2014b). A peer-reviewer also suggested using an independent measure, such as independent sampling, to verify model trends.

One commenter expressed concern with our population trend projections from Harris *et al.* (2005) because they: Used only around 20 years of data to develop growth projections for the next decade; did not account for transfer between ''management classes'' of bears (*i.e.,* habituated versus non-habituated or problem versus nonproblem); and did not account for migration between geographic zones with vastly different mortality risk (*i.e.,* Schwartz *et al.* (2006b) analysis of vital rates in three different zones).

Response—In response to a previous request for a justification of our use of linear and quadratic models in population trend estimation, a detailed explanation and justification was provided in the peer-reviewed publication (Harris *et al.* 2007, entire). Linear and quadratic regression models are fitted as an initial estimate of trend (Harris *et al.* 2007, pp. 171–172). Regression smooths variation to provide an estimate of trend representative of the population if the age distribution is relatively stable (Harris *et al.* 2007, pp. 171–172). Support for linear versus quadratic models is assessed using Akaike's Information Criterion (AIC_c; Hurvich and Tsai 1989, entire; Burnham and Anderson 2002, entire). Respective AIC_c weights of the linear and quadratic models are then used to obtain a model-averaged Chao2 estimate of the total number of females with cubs-of-the-year, using the model-averaged endpoint in the time series as the estimate for the current year. Change in trend since 1983 is assessed by examining support for the linear versus the quadratic model using AIC_c weights. Finally, a total population estimate is derived based on the estimated proportion of the total population that is represented by the estimated number of females with cubs-of-the-year. For this final step, data on vital rates (*i.e.,* survival of different sex and age classes, fecundity), as estimated from known-fate monitoring of radio-marked bears, are required. Please see Issue 28 for a detailed discussion on the estimate of unique females with cubs-of-the-year.

The IGBST is currently investigating the power of the current population estimation protocol to detect a declining trend. Primary findings will be submitted to a peer-reviewed journal later in 2017. An overview of how cumulative uncertainty in the population models are carried over into final uncertainty of estimated population growth is provided in table 2.1 of the IGBST's Demographic Workshop Report (2012, p. 20). In a rebuttal to the critique by Doak and Cutler (2014a, 2014b), van Manen *et al.* (2014, p. 328) showed that Doak and Cutler's choice of extreme mortality risk beyond age 20 and their incompatible estimate of baseline fecundity led to erroneous conclusions. We assume that the commenter is actually referring to Harris *et al.* (2006, entire). If so, these issues were addressed in that publication and other sections, of Schwartz *et al.* (2006b, entire). Twenty years of concerted efforts provides a substantial dataset for population projections, particularly for large vertebrates (few other projects on large vertebrates have such extensive datasets). We now have over 30 years of such data. The issue of management versus research bears was addressed in another chapter (see p. 9, Study Area and Methods for Collecting and Analyzing Demographic Data on Grizzly Bears in GYE) of the Monograph. Migration between the three different geographic zones used in the analyses of Schwartz *et al.* (2006b) is unknown and difficult to estimate, but radio-telemetry data do not suggest movements among the zones are common, other than the fact that some home ranges of male bears that may straddle two zones. Thus, IGBST estimates of survival and lambda for the three zones are reflective of the sampled resident bears.

For large vertebrate populations, lag effects can occur, if there is indeed

habitat decline and animals are affected by that decline. With 2016 being approximately 10 years after the peak years of whitebark pine decline and about 20 years since the decline of cutthroat trout, there is currently little evidence of a lag effect either at the GYE grizzly bear population level (population remains stable) or at the individual level (lack of evidence of changes in survival, litter size, fecundity, etc. during the last 10 to 15 years). It should be noted that observed changes in vital rates (*i.e.,* lower cub and yearling survival, slight suppression of reproduction) occurred during the late 1990s and early 2000s. Even without a lag effect, these changes in vital rates occurred prior to, or close to, the onset of whitebark pine decline; thus, there is little support for a lag effect due to changes in food resources.

The IGBST investigated the influence of ''anchoring'' the time series in 1983 versus 2002. The difference in model-averaged Chao2 estimates was negligible. For example, the 2014 estimate of females with cubs-of-the-year using the time series of 1983–2014 was 60, whereas the 2002–2014 time series resulted in an estimate of 57 for 2014. Similarly, the 2015 estimate of females with cubs-of-the-year based on the 1983–2015 time series was 56, whereas the 2002–2015 time series produced an estimate of 54 (van Manen 2016b, *in litt.*). It should be noted that there is no statistical trend based on the 2002–2015 data, supporting the interpretation of the population being stable during this time period.

In response to the comment that suggests we use additional methods to detect population trend and size, although the proposed rule (81 FR 13174, March 11, 2016) describes use of only the Chao2 method to detect population size, the IGBST uses three additional and independent methods: (1) Mark-Resight estimator (*i.e.,* capture-recapture data (IGBST annual reports)); (2) population projections from known-fate analysis (in their entirety: Schwartz *et al.* 2006b; IGBST 2012); and (3) population reconstruction (IGBST, unpublished data). Together, these four methods support the interpretation that the GYE grizzly bear population experienced robust population growth from the mid to late 1980s through the late 1990s, followed by a slowing of population growth since the early 2000s. None of these methods indicate a decline. The assertion that the bear population may be actually declining is thus not supported by data. Neither van Manen *et al.* (2016, entire) nor Bjornlie *et al.* (2014b, entire) estimated population size. van Manen *et al.* (2016, entire) used radio-monitored bears in their analysis of known-fate data to estimate vital rates, and Bjornlie *et al.* (2014b, entire) was based on home-range data of grizzly bears. Thus, the four methods currently used to estimate population trend, and upon which we base our determination, remain the best available data. Of these four methods, the model-averaged Chao2 method is currently the only method used to estimate population size and to assess recovery criterion #3.

The IGBST's primary estimates of population trajectory (*i.e.,* growth or decline) have been based on population projections using known-fate estimates of vital rates derived from radio-monitoring a representative sample of grizzly bears in the GYE (*e.g.,* see Schwartz *et al.* 2006b; IGBST 2012). Those vital rates include annual survival rates for independent male and female grizzly bears, age of first reproduction, litter size, and survival of dependent young (*i.e.,* cubs of the year and yearlings) that accompany their radio-marked mothers. The number of unique females with cubs-of-the-year estimated to be present in the ecosystem annually from IGBST observation flights and other opportunistic verified sightings do not enter into those known-fate projections. However, we can also estimate trend using the Chao2-corrected annual counts of unique females with cubs. The end point for the model-averaged result of the linear and quadratic regressions of the Chao2-corrected counts with year, along with information from our known-fate analyses, is used to derive annual population estimates. Although not a primary IGBST method for assessing trend, a key assumption for doing this based on the number of unique females with cubs-of-the-year is that the trend for this observable segment of the population (*i.e.,* females with cubs-of-the-year) is representative of trend for the whole population.

Issue 30—Several commenters offered alternative explanations of the population trend, including that: (1) Any population growth after listing occurred because of concurrent increases in food sources and road closures, rather than implementation of 1986 guidelines; (2) the population has not grown since 2000 and may even be declining below population objectives; (3) lower cub survival rates and mortalities from conflicts with hunters and livestock caused a 6 percent population decline between 2014 and 2015; and (4) further population declines are impending due to the age structure in the GYE (more older bears and fewer younger bears).

Response—We agree that implementation of the 1986 Guidelines was only one factor that increased the population trend in the GYE. However, implementation of the 1986 Guidelines by the National Forest and the National Parks improved habitat quality (*i.e.,* reduced motorized access and livestock allotments) and reduced human-bear conflicts. There is no biological way to define ''baseline'' levels for various foods because the natural foods for grizzly bears naturally fluctuate, annually and spatially, across the ecosystem. Commenters make a valid point that the number of older bears in the GYE population is increasing while the number of cubs and younger bears is decreasing, and supports the notion that GYE grizzly bears may be nearing carrying capacity in portions of the ecosystem. As van Manen *et al.* (2016, pp. 308–309) note, observations of more, older bears and suppression of recruitment support the notion of density-dependence in the GYE grizzly bear population. One consequence of density dependence indeed is that trends stabilize or possibly even decline. In response to comments that there was a 6 percent population decline between 2014 and 2015, for a long-lived vertebrate, such as grizzly bears, inference of trend based on model-averaged Chao2 estimates from one year to the next is inappropriate. Trends should be investigated over longer time periods; based on unpublished IGBST analyses of 2000 to 2015 data, analyses do not indicate a population decline (van Manen 2016b, *in litt.*). Trend analyses and population projections based on known-fate data indicate the population has indeed remained stable to slightly increasing since the early 2000s. The best available data do not indicate evidence of a population decline.

Issue 31—Several commenters and a peer-reviewer raised concerns over utilizing a new population estimation method in the future in lieu of the current methodology (Chao2). Suggestions for alternative, potentially less-biased, methods included: (1) The Mark-Resight method; (2) a model ''based on a running average of annual growth rate over'' the six preceding years; (3) a census that includes the age, sex, and location of each bear; or (4) a DNA assessment (including options that involve hair snares as done in the NCDE (Kendall *et al.* 2009), rubbing trees (Stetz *et al.* 2010), or using combined data types to increase precision (Boulanger *et al.* 2008; Abadie *et al.* 2010)). Proponents of DNA methods argued that projected costs are

comparable to those of current methods and could be significantly lower than the expensive estimates in Kendall *et al.* (2009).

Some public commenters requested that any new population estimation methodology be open to public comment prior to implementation. Some commenters and peer-reviewers were concerned that implementation of a new method could make interpretation of estimates and trends difficult and raised questions about how new estimates would be reconciled with previous estimates that used the Chao2 methodology, including a need to calibrate the mortality limits, population estimates, status review triggers, and population objectives. Commenters worried that, without this recalibration, adoption of a more accurate population estimation method would allow the States to kill hundreds of bears, while other commenters noted that new population estimation methodology should not be used to re-define what the recovered bear numbers are for future management decisions.

We received several comments about the recalibration language in Appendix C of the draft 2016 Conservation Strategy, some suggested that the same language needed to not only remain in Appendix C of the 2016 Conservation Strategy but also be included in the MOA and State plans, while others were concerned that it restricted the adaptability of future management by dictating how a new population estimator would be applied. Some commenters expressed that the lack of recalibration language in the State regulations and plans meant that adequate regulatory mechanisms were not in place.

Response—The IGBST frequently reviews their protocols and techniques for population estimation and population trend analysis. They currently use four different techniques for inference. As new techniques or approaches are reviewed for potential adoption, the technique's cost, field sampling logistics, utility to managers, and the ability to retroactively apply population estimates to previous years of data are considered. In response to specific methods raised in public comment: (1) The IGBST developed the Mark-Resight method for this purpose, and recently determined that, although the estimates are relatively unbiased, the power to detect changes in population trend was not sufficient. (2) It is unclear to what model this commenter is referring, thus we are unable to provide a more detailed response. However, the IGBST is planning to annually update vital rate estimates over the previous 10- or 15-year period (*i.e.,* temporal moving window). (3) It is impossible to truly census bear populations, especially in remote and inaccessible areas such as the GYE. The IGBST does use population reconstruction (minimum number of known live) based on an extensive dataset of capture and mortality records. (4) The IGBST considered the use of DNA sampling about 10 years ago but determined that logistics and costs (at the time, estimated at $11 million) were prohibitive. Recent advances in population estimation techniques and study design may allow for more efficient sampling, and the IGBST is currently investigating the feasibility of DNA sampling for density estimation.

The final 2016 Conservation Strategy commits to using the model-averaged Chao2 population estimator for the foreseeable future to maintain the population around the average population size from 2002 to 2014. The implementation of a new method to estimate population size within the GYE DMA would be evaluated by the IGBST and constitute a change to the Conservation Strategy, which requires approval by the YGCC and a public comment period.

The recalibration language in Appendix C was removed because it was determined to be too prescriptive as it would require data from 2002 to 2014, the period for which the model-averaged Chao2 population estimate is used as the population objective. It is likely that any new method would require data that are not currently collected, and, therefore, retroactive estimation using the new method would not be possible. The States have made a number of clearly articulated commitments through the 2016 Conservation Strategy and Tri-State MOA to maintain a recovered bear population as measured by the established demographic recovery criteria. For example, in the Tri-State MOA (Wyoming Game and Fish Commission *et al.* 2016, pp. 4, 2.a.i.), the States have agreed to manage the GYE grizzly bear population within the DMA, to *at least* within the 95% confidence intervals associated with the 2002 to 2014 long-term average grizzly bear population estimate calculated using the model-averaged Chao2 estimator (*i.e.,* 600 to 747). See Issue 21 for further discussion.

Issue 32—Several State and public commenters raised questions about the definitions of the types of mortality discussed in the proposed rule (*i.e.,* background mortality, hunting mortality, discretionary mortality, non-discretionary mortality, total mortality, unknown/unreported mortality). These commenters found the multiple terms confusing and asked for thorough definitions of each type of mortality. One commenter suggested using ''management mortality'' (mortality from hunting and management removals) and ''other mortality'' instead of our terms. The States suggested using only the term ''discretionary mortality.''

Some commenters suggested that the definitions and example calculations (*e.g.,* table 3 from the proposed rule and the example calculations for the number of individual grizzly bears that could be available for hunting harvest) included in the proposed rule should also be included in the 2016 Conservation Strategy for clarity. However, the States requested the removal of table 3 from the proposed rule.

Commenters also expressed concern about ''background mortality'' including that background mortality must take into account unknown and unreported mortalities, that we need to account for the uncertainty in the calculation of background mortality, and that we need to define the period over which the moving average of background mortality will be calculated.

Response—The proposed rule defines ''discretionary mortality'' as ''mortalities that are the result of hunting or management removals;'' thus, hunting is a form of discretionary mortality. We made changes to the discussion of human-caused mortality in *Factors B and C Combined* of the final rule to clarify this issue. As table 3 and the explanation of background mortality in the proposed rule was only an example, the YES concluded it was unnecessary to include in the 2016 Conservation Strategy. In response to comments about table 3 in the proposed rule and the definitions (*i.e.,* total mortality, background mortality, and discretionary mortality), we revised the example (table 4 in this final rule) and explanatory language to clarify. To reduce confusion, the 2016 Conservation Strategy and the final rule no longer refer to background mortality but rather total, discretionary (including hunting and management removals), and non-discretionary mortality. As stated in the Tri-State MOA, the States will annually calculate allowable discretionary mortality using the previous year's population estimate and the previous year's total mortality.

Issue 33—Commenters asserted that the methods we use to estimate unknown/unreported mortality, presented in Cherry *et al.* (2002), underestimate mortality, are outdated, are susceptible to bias, have wide

confidence intervals (which were not included in reports), and would not adequately account for deaths of bears orphaned by hunting. These commenters claimed that bias originates from: (1) The fact that the cause of a grizzly bear death changes the probability of the death being reported; and (2) variable effort in bear capture and radio-collaring. Commenters suggested that we need to account for the uncertainty in the number of unknown/unreported mortalities. In addition, a peer-reviewer suggested that we should use a sex assignment of 50 percent male and 50 percent female when determining the sex of probable or unrecorded mortalities (or assign any probable mortality as female) in order to more conservatively estimate female mortality.

Some commenters expressed concern about our ability to accurately track natural death and predation, claiming that most cub and yearling deaths are due to predation and are undocumented. One commenter disagreed with the estimates of natural death and predation provided in the proposed rule; but did not provide alternative supporting documentation.

Response—The IGBST uses the methods in Cherry *et al.* (2002, entire) to estimate unknown/unreported mortality, as it is the best available science. The IGBST does not report credible intervals for the estimate of unknown/unreported mortalities because this would substantially complicate implementation (*i.e.,* a range of mortality thresholds is not practical for managers); instead, they rely on the central tendency of the data. For decision-making, relying on the central tendency of the data is justified. Uncertainty is often interpreted to reflect a possibility of worst-case scenarios (*e.g.,* the low end of the credible interval that underestimates unknown/unreported mortality in this instance), but the tendency is towards the median and about 50 percent of estimates will be conservative (*i.e.,* above the median and, thus, overestimating unknown/unreported mortality). In the estimate of unknown/unreported mortality for independent-aged bears (*i.e.,* bears 2 years or older), all reported mortalities, including those from natural cause, are used. The method of estimating unknown/unreported mortalities indeed has a slight underestimation bias. However, all other estimations associated with calculation of mortality rates are conservative, and in several cases very conservative, such as the Knight *et al.* (1995, entire) rule set (see Schwartz *et al.* 2008, entire). Thus, the slight low bias associated with estimation of unknown/unreported mortalities is relatively inconsequential.

While there is uncertainty around estimates of unknown/unreported mortality, there is no inherent bias. The cause of death is indeed important. For example, the IGBST makes the reasonable assumption that deaths of radio-collared bears and those due to management removals are known with certainty and thus can be excluded from the Bayesian procedure that is used to estimate unknown/unreported mortalities from those documented mortalities that are discovered and reported (again excluding management removals and loss of radio-marked bears). The IGBST capture and radio-collaring efforts have been very consistent over time; while sampling this large ecosystem with its many remote and inaccessible areas is challenging, the combined effort of IGBST partner agencies is based on a well-distributed spatial sample with very little variation in annual effort over several decades of sampling. The sex ratio in the overall population is 50M:50F, and since 2002, the sex ratio for mortalities of independent-aged bears within the Recovery Zone is 51M:49F, which statistically is not different from 50M:50F (IGBST, unpublished data). However, the sex ratio of mortalities outside the Recovery Zone is biased towards males (70M:30F) and reflects the fact that range expansion is driven by males. The overall average M:F mortality ratio for the ecosystem is approximately 59M:41F and is appropriate when assigning sex to documented mortalities for which sex of the animal could not be determined.

Natural deaths of cubs and yearlings (*i.e.,* dependent young) are difficult to document, which is why the proposed rule only tracks the human-caused mortality for dependent young. Although current calculations for unknown/unreported mortality do not account for young potentially orphaned by hunting, it is extremely likely that evidence of lactation would be present on any female grizzly bear hide presented to State fish and game offices for sealing.

Regarding natural deaths of independent-aged bears, the IGBST accounts for four sources in the estimate of total mortality: (1) Documented natural mortality from radio telemetry; (2) reported natural mortality; (3) a portion of the estimated unknown/unreported mortality previously described; and (4) a portion of reported grizzly bear mortalities for which a specific cause of death was undetermined but are likely from natural causes. These mortalities from undetermined causes are also used for the estimation of unknown/unreported mortalities, which is then included in the annual estimate of total mortality.

Annual estimates of total mortality for independent female and male bears are subsequently used to assess annual mortality rates for each of those two segments of the population. Since 2010, annual estimated mortality rates (as derived from the Chao2 estimator) averaged 7.5 percent and 9.8 percent for independent female and male bears, respectively, in the DMA. These estimates are slightly higher than the average mortality rates of 5 to 6 percent derived from known-fate monitoring of radio-marked bears (IGBST 2012). The difference is likely attributable to the fact that mortality rates derived from Chao2 estimates are biased low. Using an unbiased population estimator, such as the Mark-Resight method, would result in lower mortality rates that are more in line with those derived from known-fate monitoring, suggesting that estimates of total mortality are reasonable and, therefore, estimates of natural mortalities are also reasonable.

Issue 34—We received several public comments and concerns from peer-reviewers regarding the measurement and calculation of grizzly bear mortality. Commenters asserted that using known fate monitoring to measure grizzly bear mortality (with large data sets covering long time periods) reduces the ability to detect short-term trends and produces death rates that do not match reality. Another commenter asked if our calculation of unknown/unreported mortalities includes ''possible mortalities.''

Commenters also expressed concerns about our measurement of total mortality including: (1) That the IGBST reports do not include confidence intervals on mortality rates; (2) that the IGBST does not include natural deaths in their mortality estimations; (3) that the method the IGBST uses to calculate total deaths underestimates the number of total deaths with an unknown and inconsistent degree of bias; (4) that actual total mortality is twice as high as reported levels because analysts are not accurately capturing mortality from unreported poaching and road kills; and (5) that emigration out of the DMA does not, but should, count towards total allowable mortality in the DMA or towards background mortality when calculating allowable discretionary mortality limits. One commenter suggested we use the upper bound of the 95 percent confidence interval to determine the value of unreported

mortality we include in our calculation of total mortality.

Other commenters requested that the rule include information on geographic locations of factors associated with mortality risk (*e.g.,* attractants, cover, roads, etc.), seasonal and annual distribution of these factors, and analysis on if these factors are likely to change in the foreseeable future, with or without delisting, or that detailed mortality information be publicly reported.

Response—Annual mortality rates are determined from Chao2-derived population estimates and *not* from known-fate modeling. Therefore, the comment regarding the limited ability to detect short-term trends is incorrect. Please see Issue 29 for further discussion on methods used to estimate population trend. For every reported mortality, our estimate is close to two unreported mortalities. In addition, grizzly bear mortalities are classified based on the definitions provided by Craighead *et al.* (1988), and mortality estimations include probable mortalities; however, they do not include possible mortalities.

The IGBST does not report credible intervals for estimates of unknown/unreported mortalities, which includes natural deaths, because it would substantially complicate implementation (see Issue 33 for further discussion). The IGBST includes all sources of mortality, including natural deaths, in their calculations of total mortality for independent females and males. Although the method used for estimating unknown/unreported mortalities slightly underestimates mortality, it is inconsequential because other estimations associated with calculation of mortality rates are conservative (in their entirety: Knight *et al.* 1995; Schwartz *et al.* 2008). While there is uncertainty around estimates of mortality, there is no inherent bias (see Issue 33). There is no evidence that an increase in poaching (which has remained low for several decades) has occurred. Please see Cherry *et al.* (2002, entire) for further discussion on how poaching and other causes are accounted for in calculations of unreported/unknown mortality. The assertion that emigration out of the DMA should count towards total allowable or background mortality is incorrect. Emigration out of the DMA, if it occurred, would result in a lower population estimate, which would subsequently result in a higher mortality rate if the number of mortalities stayed the same. As discussed above in Issue 33, it is reasonable to rely on the central tendency of data.

We did not find it necessary to include detailed geographic locations of factors associated with mortality risk in the proposed or final rule because the IGBST maintains the GYE grizzly bear mortality database, which is available at *https://www.usgs.gov/science/interagency-grizzly-bear-study-team?qt-science_center_objects=3#qt-science_center_objects* (last accessed on February 22, 2017), with the basic information of location, date, sex, age, certainty, and cause of death. Additional information can be already attributed, as necessary, to the grizzly bear mortality records. In addition, the availability and quality of geographic information that can be attributed to mortalities and the analytical techniques are advancing rapidly. The IGBST routinely investigates geographic, temporal, and other relationships of demographic parameters, particularly when monitoring data indicate potential changes are occurring. Therefore, if changes in mortality patterns are observed, research can be initiated to examine patterns over time for certain geographic areas, as well as potential causes, such as the study by Schwartz *et al.* (2010, entire), who developed a spatially explicit model of hazards affecting survival of grizzly bears.

Issue 35—Commenters expressed concern regarding recent increases in human-caused mortality, citing such statistics as: (1) Hunter-caused mortalities increased over the past 11 years from 3.7 bears to 10.2 bears per year; (2) total human-caused mortality has increased since 1994; (3) mortality limits for males and/or females were exceeded in 5 out of the last 7 years; and (4) the number of mortalities grew 9 to 11 percent annually between 2002 and 2011, leading to an average of 50 bears dying each year in the past 10 years, despite implementation of I&E programs in 2008. Many commenters specifically expressed concern with the ''record high'' levels of mortality in 2015, claiming that 10 percent of the GYE population died; that human-caused mortalities increased in 2015, with 61 known mortalities and at least 30 additional unknown mortalities (numbers that may underestimate total mortality by 50 percent); and that the limit for female mortality was exceeded. Many commenters provided input on the causes of these recent high mortality levels: road/railroad mortality, poaching, and lethal control from conflicts with livestock and hunters.

Commenters also suggested that 2016 mortality levels are ''unsustainable'' and could exceed the 2015 records, which reduces public confidence that mortality levels will improve upon delisting. One commenter contended that mortality could approach 200 bears annually after delisting, if bears are also killed in trophy hunts. Commenters worried if bears could withstand this additional mortality from hunting considering current high mortality levels without a hunt; many thought any additional mortality could lead to population decline. Commenters asserted that if the grizzly bear population has stabilized since 2002 while mortality rates have simultaneously increased, then the bear population is actually declining.

Many commenters also expressed concerns that the IGBST is no longer reporting violations of mortality thresholds, which the Service is required to publicly announce.

Response—First, it is important to understand that the proportion of mortalities outside the DMA is steadily increasing over time and that any population inference should be based on mortalities inside the DMA (*e.g.,* 50 bear mortalities within the DMA in 2015 vs. 61 mortalities within the entire GYE, including 50 inside the DMA and 11 outside the DMA). Second, although the total number of human-caused mortalities has increased since the early 1990s, so has the grizzly bear's population size, which is why IGBST estimates mortality rates to determine if these rates are sustainable. Third, while mortality rates within the DMA have been above mortality thresholds in several years (*e.g.,* 2015), the average has remained under the threshold over the recent period of 2010 to 2015 with 7.5 percent for independent females and 9.8 percent for independent males. And finally, causes of mortality have indeed changed over time as conservation measures were implemented and the population increased and expanded. For example, grizzly bear mortalities related to livestock depredations were almost eliminated within the Grizzly Bear Recovery Zone as livestock allotments were closed or retired during the 1980s. However, with the population expanding well beyond the boundaries of the Recovery Zone, where livestock grazing remains common, these type of mortalities have again increased. The increase in hunter-related incidents may similarly be associated with range expansion. Human access in core areas of the ecosystem is generally lower compared with the periphery. Consequently, with range expansion the probability of grizzly bear encounters with hunters during fall ungulate hunts has increased.

Regarding concerns over the level of mortality in 2015, the estimated number of annual mortalities was 25

independent females and 32 independent males, including unknown/unreported mortalities (Haroldson and Frey 2016, pp. 29–30). The mortality rate for independent females was 10.1 percent, which exceeded the allowable mortality rate of 9 percent. Importantly, the demographic recovery criterion states that this rate is not to be exceeded for *3 consecutive years* (USFWS 2017, p. 5). We documented only one year of exceedance; therefore, the criterion was not violated. The independent male mortality rate (13 percent) was under the allowable limit of 20 percent.

Total mortality from any cause, including hunting, shall not exceed thresholds as defined in the final rule and 2016 Conservation Strategy; therefore, if hunting was allowed, it would be an inclusive instead of additive source of mortality. Although independent male mortality was higher in 2016 than in 2015 (37 individuals v. 32, respectively), the mortality rate (15.5 percent (Haroldson and Frey, *in press*)) did not exceed the annual mortality threshold of 20 percent (not to be exceeded for 3 consecutive years), as outlined in the demographic recovery criteria (USFWS 2017, pp. 5–6). The independent female mortality rate for 2016 (5 percent) was also below the threshold of 9 percent. Mortality rates are currently well below the agreed upon limits set out in the revised demographic recovery criteria (USFWS 2017, pp. 5–6) and committed to by States in the Tri-State MOA. Therefore, we expect that, even if a grizzly bear hunt should occur, mortality rates will be maintained below the total mortality limits (table 2).

The assertion that the bear population may be actually declining is not supported by data. See Issue 29 for additional detail.

The IGBST did not include in their Annual Report for 2015 whether mortality thresholds were exceeded because the demographic recovery criteria were under revision. They will report if mortality rates are under or over sustainable rates, as measured by the revised demographic recovery criteria, in future annual reports, which will be available at *https://www.usgs.gov/centers/norock/science/igbst-annual-reports?qt-science_center_objects=1#qt-science_center_objects.*

Issue 36—Both commenters and peer-reviewers raised concerns over our ability to detect trends in vital rates and our interpretation of these trends. A peer-reviewer noted that monitored individuals may be more susceptible to capture and may not serve as an accurate representative sample in regards to the measurement of vital rates. Commenters also noted that negative trends in vital rates, and thus population declines, may not be detected until it is too late, citing that there has been a decrease in cub and yearling survival since the early 2000's, and that there is uncertainty associated with the ecological factors that may be contributing to this decline in vital rates. Finally, one commenter asked if the various reproductive parameters co-vary and, if they do, is it in a linear or non-linear manner.

Response—Sampling the GYE grizzly bear population for known-fate monitoring is challenging. Long-term capture efforts are not perfect but are designed to obtain a representative sample of the population and represent the best available scientific method for the question at hand. While some individuals may be more susceptible to capture, there is no indication that this factor has caused a bias in estimation of vital rates. There are no studies or data suggesting that bears which are more susceptible to capture have lower or higher survival compared with bears that are less susceptible. On the contrary, population projections derived from vital rates for the period from 1983 to 2001 indicated robust population growth of 4 to 7 percent (Harris *et al.* 2006, p. 48), which was similar to the 4 to 5 percent trend obtained for counts of unique females with cubs-of-the-year for the same period (Harris *et al.* 2007, p. 175). Similarly, when a change in trajectory and a slowing of growth for counts of females with cubs-of-the-year was detected in the early 2000s, a reanalysis of vital rates for the period from 2002 to 2011 corroborated the slowing of population growth, producing population projections based on known-fate data indicating a 0 to 2 percent growth. The concordance between these two unrelated and distinct methods (*i.e.,* estimates of females with cubs-of-the-year and population projections based on known-fate data) used to estimate trend, and as applied during the two different periods, lends confidence that vital rates derived from known-fate monitoring are reasonable and unbiased. Additionally, we have found no evidence that the number of captures per individual bear affected survival estimates of independent-aged bears (IGBST, unpublished data).

There is a lag time between when a change in trend occurs and when it may be detected. However, the current monitoring system effectively identified that a change in the population trajectory had occurred, which triggered the IGBST to conduct a comprehensive biology and monitoring review; this review led to the finding that cub and yearling survival and a reproductive parameter had declined, which led to further investigations about the potential causes for these changes. Those potential causes were investigated in detail as part of the IGBST's Food Synthesis project and indicated associations with bear density (cub survival and reproductive transition decreased as bear density increased), but not with decline of whitebark pine. Regardless, the issues of trend detection are important. The IGBST is currently investigating the ability to detect (based on the Chao2 estimator) when population estimates have reached specific population thresholds and the degree to which population thresholds may be exceeded, both in time and population size, before they are detected. Reproductive parameters in wildlife populations, including bear populations, typically co-vary and often in a non-linear manner. Depending on the complexity of these relationships, the covariance of parameters may be difficult to accurately estimate.

Issue 37—Both the public and peer-reviewers presented comments about our discussion and analysis of the GYE's carrying capacity for grizzly bears, including raising concerns that figure 1 of the proposed rule is an oversimplification of a population at carrying capacity and requesting that an explanation of the additional variables influencing carrying capacity (*e.g.,* food availability and emigration in search of food, mates, or territory) be included. One commenter noted that a graph illustrating how the Chao2 estimate of the GYE grizzly bear population is leveling off might provide a clearer demonstration of carrying capacity.

Some commenters questioned whether carrying capacity has been reached since (1) grizzly bears occupy only 25 percent of the GYE; (2) there is inherent difficulty in calculating carrying capacity; and (3) a population that is increasing at a rate of 3 to 4 percent per year and for which harvest needs to be adjusted to maintain mortality levels at 10 to 22 percent are not parameters characteristic of a population at carrying capacity. In addition, a few commenters questioned if our conclusion that the GYE grizzly bear population has reached carrying capacity applied within the PCA, the DMA, or the entire GYE. Conversely, other commenters expressed support that carrying capacity has been reached based on: (1) The preponderance of the best available science; (2) the stability of reproduction inside YNP; and (3)

increased grizzly bear attacks on humans in recent years. Commenters worried that these attacks would increase and that male grizzly bears would start to kill dependent grizzly bears if the population keeps growing.

One commenter and several peer-reviewers suggested alternative hypotheses to our claim that the GYE population is approaching carrying capacity: (1) That a decrease in food availability (as mentioned in van Manen *et al.* (2016, p. 309)) may be the driver behind a slowing growth rate in the GYE grizzly bear population, the increase in grizzly distribution, and the increase in human-caused mortalities; and (2) that grizzly bears in the GYE may have reached a human *social* carrying capacity. These commenters also suggested increasing habitat to allow for population expansion and recovery.

Response—We have made clarifications in the carrying capacity discussion of the final rule (see *Population Ecology—Background; Population and Demographic Recovery Criteria;* and *Changes in Food Resources*) and the 2016 Conservation Strategy (see Population Trend). Although figure 1 of the proposed rule was a simplification of a population at carrying capacity (expressed as K), it is necessary to explain the general principles behind the concept of K. In addition, the narrative of carrying capacity addresses the complexity of this issue, including an explanation of the variables that some commenters proposed we include (*i.e.,* density-dependent and density-independent effects) and the difficulty in measuring carrying capacity. We disagree that a graph illustrating how the Chao2 estimate of the GYE population is leveling off may be a clearer demonstration of carrying capacity, because the population has only recently approached carrying capacity compared to a population that has been fluctuating around carrying capacity as conveyed in figure 1 of the proposed rule.

While one commenter noted that grizzly bears occupy only 25 percent of the GYE, we note that suitable habitat is roughly 24 percent of the total area within the GYE DPS boundaries, of which grizzly bears occupy 90 percent (see Issue 22). We acknowledge in the proposed rule the inherent difficulty in calculating carrying capacity. As the population has approached carrying capacity, the population growth rate has naturally slowed with the most recent trajectory using the Chao2 estimator showing no statistical trend within the DMA for the period 2002 to 2014 (van Manen 2016a, *in litt.*). The conclusion that the GYE grizzly bear population has reached carrying capacity applies within the DMA, as that is the area in which the population is monitored for population size, population trend, and mortality.

Studies by the IGBST provide strong support for a density-dependent effect for the leveling off of the population. Discussion of the Food Synthesis Report (see *Factor E,* above) addresses comments that suggested that a decrease in food availability may be the driver behind the slowing growth rate of the GYE grizzly bear population. Although van Manen *et al.* (2016, p. 309) recognized that a decreased carrying capacity was an alternative explanation for demographic changes in the GYE population, they also indicate the scientific evidence is not strong:

> If bears were responding to a decline in carrying capacity, however, we would have expected home-range size and movements to have increased (McLoughlin *et al.* 2000), bears to have relied on lower energy food resources (McLellan 2011), and body condition to have declined as a consequence (Rode *et al.* 2001, Robbins *et al.* 2004, Zedrosser *et al.* 2006). To date, there is little support for these conditions in the Yellowstone Ecosystem: female home ranges have decreased in size and are less variable in areas with greater bear densities (Bjornlie *et al.* 2014b), daily movement rates and daily activity radii have not changed for either sex during fall (Costello *et al.* 2014), bears continue to use high-quality foods (Fortin *et al.* 2013), and body mass has not declined (Schwartz *et al.* 2014). As we discussed previously, percent body fat among adult females has not declined since the early 2000s (IGBST 2013, Schwartz *et al.* 2014) and, regardless, this effect would be consistent with either interference or exploitation competition and would not explain the changes in vital rates that occurred much earlier than the declines in foods. Current evidence indicates bears showed a functional response to declines in whitebark pine (Costello *et al.* 2014) and cutthroat trout (Fortin *et al.* 2013) and compensated for the loss of these particular foods through diet shifts Schwartz *et al.* 2014).

The IGBST data does not support the alternative hypothesis that human social carrying capacity has been reached and is contributing to the slowing of population growth. On average, total mortality rates over the last 10 to 15 years have not exceeded established mortality thresholds and there is no evidence of an increase in poaching, which has remained low for several decades. The DMA is based on an IGBT assessment of an area ''sufficiently large to support a viable population in the long term'' (IGBST 2012, p. 42). The 2016 Conservation Strategy incorporates adaptive management and monitoring of population vital rates, habitat standards, and major foods into management decisions to ensure that the GYE grizzly bear DPS remains recovered.

Issue 38—Some commenters questioned our interpretation of bear density in the GYE. Many commenters claimed that bear density is actually decreasing in the GYE because the population has stabilized or decreased since the early 2000s while grizzly bear range has simultaneously increased by as much as 40 percent (*i.e.,* the same number of bears are spread across an ever-increasing area) and that such declines in density are suggestive of habitat decline and decreased carrying capacity. One commenter took issue with the methods we used to assess density, stating that researchers have not reviewed our density index to confirm its reliability.

Commenters also raised concerns about the factors we used to evaluate the relative influence of density-independent and density-dependent effects on grizzly bear population dynamics in the GYE, suggesting: (1) That of the four factors we analyzed, only one factor (home range size) differed between the analyses of density-dependence and density-independence, and, therefore, the other three factors (decreased cub and yearling survival, increased age of first reproduction, and decreased reproduction) cannot be used to distinguish between the influence of density-dependent and density-independent effects; (2) that we only explained one of these four factors (cub survival); and (3) that we did not account for temporal changes in the abundance of key foods and habitat. Commenters thus questioned the causal link we suggested between density-dependence and declining vital rates, and one peer-reviewer suggested we review our use of any words suggesting causality, as opposed to association, in our density-dependence analysis.

Response—The hypothesis that population density in the core area has decreased and that the same number of bears is spread across an increasing area is not supported by the best available data, including that:

(1) The number of females with cubs-of-the-year in YNP showed a gradual but steady increase from 1973 through 2015, while the number of females with cubs-of-the-year observed outside of YNP increased at a much higher rate starting in the late 1980s (IGBST, unpublished data) (see figure 4 in the 2016 Conservation Strategy).

(2) Home-range and movement data do not support the interpretation that bears are leaving the core of the

ecosystem; additionally, from a life-history aspect, range fidelity for adult female grizzly bears is high and female offspring also tend to establish their ranges adjacent to or near their maternal ranges.

(3) Recent range expansion has occurred beyond the DMA, and thus beyond the area where the IGBST conducts population monitoring. However, we believe the population is close to carrying capacity inside the DMA and expect continued range expansion through bear dispersal.

(4) The IGBST uses four independent methods to estimate population size and/or trend (see Issue 29).

In regard to the density index, it was peer-reviewed (contrary to the comment submitted that it was not), published, and presented in detail in both Bjornlie *et al.'*s (2014b) Supplemental Materials and in van Manen *et al.* (2016, pp. 303–304). The basis for the density index is a spatially explicit population reconstruction—thus, it incorporates capture and home range information from much more than bears trapped in any one year.

In response to comments about our conclusions from our analysis of density-independent and density-dependent effects on grizzly bear population dynamics in the GYE we added clarifying language in this rule (see *Population Ecology—Background* and *Changes in Food Resources*) and 2016 Conservation Strategy (YES 2016a, pp. 49–50).

In response to the comment suggesting we review our use of words suggesting ''causality'' as opposed to ''association'' in our density-dependent analysis, we clarified that density-dependent effects are the likely cause of the recent slowing in population growth factors rather than ''associated with''.

Habitat Management Issues (Factor A)

Issue 39—Regarding the delineation of boundaries, particularly for the DMA and PCA, some commenters: (1) Questioned why some currently occupied habitat was excluded from the DMA; (2) recommended that DMA and PCA boundaries be expanded to accommodate more potential habitat, including all designated wilderness lands adjacent to the proposed DMA; (3) suggested that the DMA boundaries should not be changed post-delisting; or (4) noted that the PCA is based on early, rough estimates of the grizzly bear recovery zone, which provided habitat for 229 bears and was never updated. Lastly, some commenters suggested that the Service should first determine how many bears are needed for recovery, then delineate enough suitable habitat to meet those needs.

Response—The DMA boundaries are based on the best available science from the IGBST (2012, pp. 41–44). While the Recovery Plan identified the Recovery Zone as the ''area within which the population and habitat criteria . . . will be measured'' (USFWS 1993, p. 17), the IGBST recommended that maintenance of a grizzly bear population that extends outside of those boundaries into adjacent suitable habitat would help ''ensure the long-term viability of this population'' (IGBST 2012, p. 41). The IGBST then examined the Service's suitable habitat boundary, population monitoring data, and mortality data to identify boundaries that would be ''. . . sufficiently large to support a viable population in the long term, such that mortalities beyond it could be excluded from consideration'' (IGBST 2012, p. 42). Because the Service's suitable habitat line is based largely on mountainous ecoregions, the IGBST recommended including valley floors surrounded by suitable habitat in the DMA so that the disproportionate mortality that may occur in those areas (*i.e.,* the 'edge effect') is not excluded from the overall picture of population health and monitoring.

The IGBST used the average annual activity radii of independent female grizzly bears to buffer and smooth the boundaries of suitable habitat so that the DMA would encompass areas outside of suitable habitat that were likely to be used by grizzly bears on a regular basis. This is the process by which areas such as the Upper Green River were included within the DMA boundaries. Conversely, because this quantitative technique smoothed the boundaries of suitable habitat and did not attempt to define suitable habitat itself, it is also the reason some areas in the southern Wind River Range were not included in the DMA even though they are found within Wilderness Areas. These were areas that did not meet the definition of suitable habitat because they possessed high mortality risk due to large, contiguous blocks of sheep allotments. The Service adopted the IGBST's recommended DMA boundaries in the Revised Demographic Criteria (USFWS 2017, entire). The Big Sandy and Popo Agie areas are included in the DMA because we consider most of the Wind River Range to be suitable habitat for grizzly bears in the GYE due to the large percentage of Wilderness. Lastly, recovery plans are not regulatory documents and are instead intended to provide guidance to Federal agencies, States, and other partners on criteria that may be used to determine when recovery is achieved.

Issue 40—Both public commenters and peer-reviewers thought our definition of suitable habitat was qualitative, too weak, and lacked rationale. Public commenters provided additional comments regarding our definition of suitable habitat, including that it: (1) Did not, but should, include lands with sheep allotments and other livestock operations that can increase human-bear conflicts; (2) does not identify what proportion of suitable habitat is ''core habitat'' versus ''edge habitat;'' (3) does not specify which areas (core or edge habitat, suitable or unsuitable habitat) are needed to sustain the GYE population's viability; (4) does not explain the meaning of ''support survival;'' (5) excluded important potential habitat on public lands adjacent to the DMA; (6) excluded ''some habitat outside the DMA that is already occupied;'' and (7) incorrectly excluded currently unoccupied areas based on the potential ''social intolerance'' for bears in these areas. Moreover, commenters noted that social acceptance is ephemeral and wondered how plans, regulations, and the 2016 Conservation Strategy would allow for the changing definition of ''socially acceptable.'' One commenter suggested using ''spatially dynamic boundaries'' in our definition to allow for geographical shifts in habitat types and changing food locations. Finally, one peer-reviewer requested that we treat all of the three characteristics of suitable habitat equally, and provide more detail on characteristics 1 and 2, in our discussion of suitable habitat.

In addition, other commenters were uncertain as to how we defined unsuitable habitat and wondered if unsuitable habitat was ''non-habitat,'' ''edge habitat,'' habitat with a certain number of human-bear conflicts, areas where ''reasonable levels of bear/human conflict precautions do not suffice to prevent the death of a substantial fraction of bears entering this area,'' or areas that are population sinks. One commenter suggested that the Service makes unsupported claims that bears in unsuitable habitat are more ''transient'' and did not define ''transient.'' Commenters requested demographic data on each area of unsuitable habitat, presuming these areas are sinks, as well as information on the methods managers used to determine the number of bears in unsuitable habitat and how much time each bear spent in unsuitable habitat. Other commenters worried that declaring habitat unsuitable because of the high risk of mortality would become a ''self-fulfilling prophecy'' and that

bears entering unsuitable habitat may no longer be a member of a viable population.

One commenter requested two additional visuals: (1) A map that overlays locations of bear deaths with habitat suitability, the ''range'' of viable populations, and the home ranges of the dead bears; and (2) a map that shows which unsuitable habitat does not meet grizzly bear needs because of concerns about mortality risk and which unsuitable habitat does not meet grizzly bear needs for other reasons. Another commenter asked for further details on what levels and kinds of management to reduce conflicts would be considered ''reasonable and manageable,'' specifically: I&E; efforts to reduce the availability of attractants; live-trapping and removal of conflict bears; and aversive conditioning of conflict bears.

Response—Our definition of suitable habitat is based on biological criteria and the results of previously published research about grizzly bear mortality risk and biological needs. We used the Middle Rockies Ecoregion as a surrogate for habitat quality/capacity, an approach that is supported by many previous studies which have found that mountainous regions generally possess the habitat components necessary for grizzly bear viability, including hiding cover, topographic variation necessary to ensure a wide variety of seasonal foods, steep slopes used for denning, and remoteness from humans (Craighead 1980, pp. 8–13; Knight 1980, pp. 1–3; Judd *et al.* 1986, pp. 114–115; Peek *et al.* 1987, pp. 160–161; Aune and Kasworm 1989, pp. 29–58; Merrill *et al.* 1999, pp. 233–235; Pease and Mattson 1999, p. 969; Linnell *et al.* 2000, pp. 403–405; Mattson and Merrill 2002, p. 1128).

Our determination that large, contiguous blocks of sheep allotments were not suitable for grizzly bears was biologically based on mortality rates. Scattered, small, and isolated sheep allotments were included in suitable habitat and considered in our threats analysis under *Factor A,* above. The GYE grizzly bear population's long-term viability is ensured without their occupancy of areas that currently contain large, contiguous blocks of sheep allotments because of the habitat protections inside the PCA and the large percentage of suitable habitat outside the PCA (60 percent) that is classified as Wilderness (6,799 km^2 (2,625 mi^2)), WSA (708 km^2 (273 mi^2)), or IRA (6,179 km^2 (2,386 mi^2)). Even with the exclusion of these large, contiguous blocks of sheep allotments, most of the Wind River Range met the definition of suitable habitat. The Palisades may be outside of suitable habitat but the Idaho grizzly bear management plan specifically identifies this area as ''likely to be inhabited by grizzly bears'' (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 8–9). States have no plans or intentions of excluding non-conflict grizzly bears from Wilderness, WSAs, or IRAs on public lands and have made it clear that their management efforts outside of suitable habitat and the DMA will focus on conflict response in areas with higher human densities (*e.g.,* subdivisions) (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 8–9; MFWP 2013, p. 44; WGFD 2016, pp. 12, 20).

The presence of grizzly bears in places with high levels of human activity and human occupancy results in biological effects to grizzly bears in terms of increased mortality risk and displacement. The level of this effect is directly related to the location and numbers of humans, their activities, and their attitudes and beliefs about grizzly bears. The consideration of human activities is fundamental to the management of grizzly bears and their habitat. While it is true that the current distribution of grizzly bears extends outside of the DMA into unsuitable habitat, the records of grizzly bears in these areas are generally due to recorded grizzly bear-human conflicts or to transient animals, not reproductive females with offspring. For instance, between 1985 and 2014, only 2.1 percent of all sightings of unduplicated females with cubs-of-the-year were outside of the DMA (Haroldson 2016, *in litt.*). These areas are defined as unsuitable due to the high risk of mortality resulting from these grizzly bear-human conflicts. These unsuitable habitat areas do not permit grizzly bear reproduction or survival because bears that repeatedly come into conflict with humans or livestock are usually either relocated or removed from these areas.

Our definition of suitable habitat is biologically based on the best available science and not on ''social intolerance.'' The 2016 Conservation Strategy specifies strategies to manage grizzly bear-human conflicts, and for ongoing I&E programs, both of which foster social tolerance (YES 2016a, pp. 86–95). The adaptive management approach described in the 2016 Conservation Strategy will allow management agencies to make changes, if necessary, to I&E efforts and conflict management in response to potential impacts of changes in social tolerance.

Our analysis of suitable habitat was a quantitative, broad-scale habitat assessment. As such, its purpose was to provide an understanding of the broad trends in habitat distribution, not to address the nuances of changing food sources or dynamic mortality risk as ''spatially dynamic boundaries'' would. While we appreciate this commenter's suggestion, we conclude that the spatially explicit survival modeling done by the IGBST is adequate to address these concerns (see Schwartz *et al.* 2010). We have not assigned numerical quality scores to habitats based on grizzly bear body condition or productivity because of the uncertainties surrounding such calculations, instead concluding that it was appropriate to use a more generalized, coarse-scale interpretation of what habitat would meet grizzly bear needs. Other models that predict where suitable grizzly bear habitat occurs within the GYE produced results similar to ours (Noss *et al.* 2002, p. 903; Merrill and Mattson 2003, pp. 182, 184).

The Act does not require us to quantify the proportion of suitable habitat that is ''core'' versus ''edge'' habitat; however, we did consider edge effects in our analysis and chose not to include isolated patches and strips of land as suitable habitat because of the potential for higher mortality. The IGBST tracks mortality and associated causes (see Issue 34). Historically, increased human-caused mortality risk was associated with motorized access routes, which led to implementation of motorized access route standards (YES 2016a, pp. 54–71; *Factor A* analysis). Currently the leading causes of human-related mortalities are hunting-related (including mistaken identity kills by black bear hunters and self-defense), and management removals due to either livestock depredations or site-specific human-bear conflicts, which are not geographically associated with an ''edge'' effect. Suitable habitat, as identified in the proposed and final rule, is sufficient to maintain a recovered grizzly bear population. Please see the *Recovery Planning and Implementation Suitable Habitat* section of this final rule for the definition and a discussion of suitable habitat, including all three of the characteristics of suitable habitat and how it was mapped. Because population sinks may occur in narrow, linear valley floors that are not suitable habitat but are largely surrounded by suitable habitat (*i.e.,* ''edge effect''), these were included in the demographic monitoring area, the area in which the population is monitored, and mortality limits will be applied. See *Factor A,* above, for further discussion.

The IGBST's annual reports include maps of mortality locations that show

the distribution of grizzly bear mortalities in the GYE and the boundaries for the PCA and the DMA. As only 22.3 percent of known and probably independent-aged grizzly bears that died from 2002 to 2014 were collared at the time of their death (Haroldson 2017a, *in litt.*), it is not possible to show the home ranges of all dead bears. Please see the 2016 Conservation Strategy for discussion on conflict management (YES 2016a, pp. 86–91) and I&E efforts (YES 2016a, pp. 92–95) to reduce conflicts.

Issue 41—Commenters expressed concerns about our analysis of the relationship between habitat availability and grizzly bear population viability. A peer-reviewer expressed concerns that our discussion of habitat management in the proposed rule focused primarily on preventing human-caused mortality, rather than on systematically identifying the biological features characteristic of important grizzly bear habitat. This peer-reviewer requested that we provide information on the biological features of habitats that different ages and sexes of grizzly bears use during each season using the quantitative methods from Proctor *et al.* (2015). The peer-reviewer also suggested that these resource selection models could be used to bolster the definition of suitable habitat. One commenter believed that the Service did not properly evaluate the amount of habitat necessary to maintain a viable grizzly bear population despite available science on this subject (*e.g.,* Noss *et al.* 1999). The commenter also believed that the Service failed to perform spatially explicit analysis of vegetation and habitat productivity, as in the Cumulative Effects Model (CEM), which the commenter claimed we inappropriately stopped using without scientific explanation or adequate replacement. One commenter did not believe we adequately assessed relationships between habitat features and vital rates and that we did not explain the time lags in this analysis.

Response—Our habitat management standards rely heavily on reducing anthropogenic influences and minimizing grizzly bear-human conflicts because excessive human-caused mortality and subsequent population decline was the primary factor that led to the species' original threatened listing in 1975. For a detailed explanation of this rationale please refer to the *Habitat-Based Recovery Criteria* section of this final rule and Chapter 3 of the 2016 Conservation Strategy (YES 2016a). Schwartz *et al.* (2010, p. 658) used 21 years of data and nearly 12,000 known grizzly bear locations to create a habitat-based risk model that accounted for the habitat features associated with grizzly bear survival throughout the GYE. This risk model examined how motorized use of roads, productivity and seasonality of high-calorie foods, site developments, livestock allotments, number of homes on private lands, elk hunting units, and season influenced grizzly bear survival on the landscape (Schwartz *et al.* 2010, pp. 656–658). The resulting models identified source and sink habitats throughout the GYE and further supported our management approach of limiting motorized use and developed sites to improve grizzly bear survival (Schwartz *et al.* 2010, p. 659).

Schwartz *et al.* (2010, entire) did not use resource selection functions to develop their model because resource selection functions are not always proportional to the true probability of use and, therefore, are not always the best way to describe habitat relationships (Keating and Cherry 2004, p. 788). However, in principle, the spatially explicit risk model of Schwartz *et al.* (2010, pp. 656–658) can be thought of as a special case of a resource selection function, but with the variable of interest being survival rather than habitat selection. In fact, we conclude that the risk model is more relevant for decision-making because it actually measures a demographic parameter (*i.e.,* survival) as opposed to habitat selection, which may or may not influence demographics. We have reviewed Proctor *et al.* (2015, entire), and, while we acknowledge it is a useful tool for predicting areas of grizzly bear use, we find the results of Schwartz *et al.* (2010, pp. 658–661) more appropriate for making management decisions because Schwartz *et al.* (2010, pp. 658–661) linked habitat features to actual grizzly bear survival on the landscape.

Although Boyce *et al.'*s (2001, entire) population viability analysis did not consider possible changes in habitat, based on female with cubs-of-the-year trends from 1983 to 1997, they found that the GYE grizzly bear population had a 1 percent chance of going extinct in the next 100 years. The GYE grizzly bear population has continued to expand in both population size and distribution since this analysis. Secure habitat, as discussed by Noss *et al.* (1999, pp. 101–102), is the key to reducing human-caused mortality. Secure habitat will be provided through application of the 1998 baseline inside the PCA and through Wilderness, WSAs, and IRAs that cover 60 percent of suitable habitat outside the PCA. Mortality limits necessary to maintain a recovered population, as set forth in this rule, the 2016 Conservation Strategy, the revised demographic recovery criteria, and the Tri-State MOA, will be applied within the DMA. Please see Issue 40 and *Factor A* for further discussion of the habitat necessary to maintain a viable grizzly bear population.

Appendix E of the 2016 Conservation Strategy explains why the CEM is no longer the best available science and that the Motorized Access Model, established concurrently with the CEM, will be the tool used to project impact analysis (YES 2016b). The Motorized Access Model calculates and monitors secure habitat and motorized route density. The 2016 Conservation Strategy incorporates the IGBST's long-term monitoring data of population vital rates, habitat standards, and major foods and will be used to inform management decisions on maintaining a recovered GYE population. Although lag effects can occur in large vertebrate populations affected by habitat declines, there is little evidence of a lag effect at the grizzly bear population or individual level in response to changes in food resources. The IGBST's current monitoring system effectively identified a change in the species' population trajectory, which subsequently triggered the IGBST to conduct a comprehensive biology and monitoring review. See Issue 36 for further discussion on lag effects, vital rates, and habitat features.

Issue 42—Peer-reviewers and commenters expressed concern with our definition of secure habitat. Peer reviewers provided requests for additional rationale for our use of 10 acres as the minimum size in the definition of secure habitat; and suggestions to change our requirements for lake size in defining secure habitat since grizzly bears do not use most open water (and thus any lake, regardless of size, should be classified as insecure). A commenter worried that we used a definition of secure habitat from the USFS's 2006 EIS, which does not contain a justification for the definition.

Commenters and peer-reviewers provided the following alternative means of defining secure habitat: (1) Defining ''microscale'' security areas as approximately 28.3 km^2 (10.9 mi^2) in size that have a 2- to 4-km (0.8- to 1.5-mi) buffer from roads or human facilities, as recommended in Mattson (1993); (2) increasing minimum core security areas to approximately 10 km^2 (6.2 mi^2) to allow for dietary flexibility and to fully encompass the average daily movements of an adult female grizzly bear (Gibeau *et al.* 2001); (3) ensuring secure habitat is at least 500 meters (m) (1,640 feet (ft)) from areas of high human use, defined as areas with more than 100 human visits per month;

and (4) including a buffer along lake shorelines that ''represents the actual area used by grizzly bears.''

Peer-reviewers and commenters provided suggestions on the management of secure habitat, including that: (1) Any future changes to secure habitat, and subsequent mitigation efforts, need to ensure that secure habitat is distributed across the landscape in a way that does not cause habitat fragmentation and that facilitates movements of bears both within and between bear management units (from a peer-reviewer); (2) the 2016 Conservation Strategy's guidelines for road construction on secure habitat, signage, and crossing structures are vague, especially about who monitors road density, makes decisions about additional roads, and pursues mitigation; (3) the proposed rule and the 2016 Conservation Strategy were not consistent in how they discussed USFS maintenance of secure habitat; and (4) the 2016 Conservation Strategy's provisions that allow only temporary reductions in the amount of secure habitat seem to apply only to Federal projects and leave open what could happen to secure habitat affected by State or county road projects (especially if they are emergency projects or broad-scale projects that could affect more than one BMU).

Response—Our definition of secure habitat includes areas as small as 10 acres in size because the IGBST and YES concluded that all secure habitats are important for grizzly bears in the GYE, regardless of size, particularly in peripheral areas. We remain confident in our definition of secure habitat because Schwartz *et al.* (2010, p. 661) were able to demonstrate a direct link between this definition and grizzly bear survival in the GYE. If we heeded the recommendations of commenters and enlarged the minimum size of secure habitat to 10 or 28.3 km^2 (3.9 or 10.9 mi^2), the end result would be that thousands of acres of secure habitat would no longer be considered secure and would, therefore, not be subject to the ''no net loss'' standard. By using a smaller minimum acreage requirement, we are not excluding any of the larger blocks of secure habitat.

Lakes are not automatically considered secure habitat. Instead, secure habitat is based on the presence or absence of motorized access. Lakes larger than 2.6 km^2 (1 mi^2) are removed from the analysis and are not considered either secure or non-secure habitat. Security of lakes smaller than 2.6 km^2 (1 mi^2) is evaluated by the presence/absence of motorized roads and trails within the general vicinity. The negative effect of humans on grizzly bear survival and habitat use are well documented (Harding and Nagy 1980, p. 278; McLellan and Shackleton 1988, pp. 458–459; Aune and Kasworm 1989, pp. 83–103; McLellan 1989, pp. 1862–1864; McLellan and Shackleton 1989, pp. 377–378; Mattson 1990, pp. 41–44; Mattson and Knight 1991, pp. 9–11; Mattson *et al.* 1992, pp. 436–438; Mace *et al.* 1996, p. 1403; McLellan *et al.* 1999, pp. 914–916; White *et al.* 1999, p. 150; Woodroffe 2000, pp. 166–168; Boyce *et al.* 2001, p. 34; Johnson *et al.* 2004, p. 976; Schwartz *et al.* 2010, p. 661). In light of this, the importance of secure habitat, simply defined as a function of distance from roads, is indisputable. Therefore, if a small lake is farther than 500 m (1,640 ft) from a motorized access route, it is deemed secure habitat; otherwise, portions of lakes within 500 m (1,640 ft) of motorized access routes are considered non-secure habitat.

We do not think it is necessary to modify our definition of secure habitat to exclude areas within 500 m (1,640 ft) of high human use. Federal agencies lack sufficient resources and data needed to measure the intensity of human-use for every road and trail throughout the ecosystem. Instead, for grizzly bear purposes, motorized access is a surrogate measure of human presence on the landscape and one that can be reliably tracked via GIS. Research indicates that non-motorized trails do not significantly affect grizzly bear survival, and that survival was better explained by the presence of motorized routes (Schwartz *et al.* 2010, p. 659). Those areas farther than 500 m (1,640 ft) from the nearest motorized access are considered secure habitat.

We agree with the comment that any changes to secure habitat should ensure it is distributed across the landscape in a way that does not cause habitat fragmentation. The 2016 Conservation Strategy directs that, on the rare occasions when there are projects inside the PCA that require the construction of new roads (*i.e.,* permanent changes to secure habitat), any replacement of secure habitat must be of equivalent quality and quantity (YES 2016a, pp. 61–63). Grizzly bear habitat connectivity is one of the many factors that would be assessed in determining if that replacement habitat was of equivalent quality. Additionally, any project on public lands within suitable habitat outside the PCA that requires highway construction would evaluate the impacts of this motorized use on grizzly bear habitat connectivity (YES 2016a, pp. 82–83).

The NPS and the USFS manage the majority of lands within the GYE and are responsible for managing road construction on their lands, including monitoring road density, making decisions about additional roads and pursuing mitigation. Land and resource management plans for National Forests and National Parks in the GYE have incorporated additional habitat standards and other relevant provisions of the 2016 Conservation Strategy (USDA FS 2006b, entire; YNP 2014, p. 18; GTNP and JDR 2016, p. 3) and will guide decisions about road management. The allowance for temporary reductions in secure habitat applies only to areas inside the PCA, of which 97.9 percent of the land is Federally owned. With only 2.1 percent of the land in private and other ownerships, we conclude that any future State or county road projects would not substantially affect secure habitat. Additional specificity and timelines will be provided in State grizzly bear management plans, forest plans, and other appropriate planning documents for areas outside the PCA.

Issue 43—Many public and State commenters and peer-reviewers commented on the adequacy of the current amount of grizzly bear habitat and habitat protection. While the States emphasized that current habitat protections are adequate, some commenters thought otherwise, claiming, in regard to both the amount of habitat and level of protection, that (1) the amount of grizzly bear habitat is ''shrinking'' and insufficient to support long-term population growth; (2) more secure habitat should be protected now to compensate for potential future losses; (3) managers must maintain habitat conditions to keep grizzly bear populations stable; (4) one-third of occupied habitat lacks any habitat protections; (5) grizzly bears would lose 2.1 million acres (or 23 percent) of occupied habitat under State regulations; and (6) the States should be required to manage for increasing habitat. A peer-reviewer recommended that managers develop plans to control important habitat components (*e.g.,* distribution and abundance of ungulates). Lastly, one commenter requested additional information on the current amount of various types of habitat and how this will change in the future (such as the amount of unsuitable edge habitat, non-habitat, and denning habitat).

Response—We disagree that the amount of grizzly bear habitat is shrinking and insufficient to support long-term population growth. We acknowledge that it is difficult to

specify the precise size of the area necessary to support a population of grizzly bears because these animals are long-lived, opportunistic omnivores whose needs for foods and space vary depending on a multitude of environmental and behavioral factors, and on variation in the experience and knowledge of each individual bear. Therefore, to guide us in establishing habitat criteria that will maintain a healthy population into the future, we evaluated the past habitat factors that had produced an increasing GYE population in both numbers and range. Habitat protection standards and monitoring protocols in the Conservation Strategy call for no net loss of secure habitat with respect to 1998 conditions, which are believed to have supported and contributed to robust GYE population growth observed during 1983 to 2001. Habitat standards, as they apply to the 1998 baseline, impose measurable side boards on allowed levels of human activity inside the PCA and establish a clear benchmark against which future improvements and impacts to habitat can be measured. Although approximately 23 percent of the current range occurs outside of the DMA, our assessment of suitable habitat is that it contains adequate habitat quality and quantity to support a recovered grizzly bear population (see the *Suitable Habitat* section of this final rule and Issue 41 for further discussion on suitable habitat). We conclude that increases in habitat are not necessary to support a recovered population and that our habitat protection criteria are adequate and biologically sound.

Regarding the comment suggesting managers should develop plans to control important habitat components, the GYE National Forests and National Parks have incorporated the habitat components outlined in the Conservation Strategy into their compendia, and the National Forests' 2006 Forest Plan Amendment will go into effect upon delisting, as stated in the amendment (see Issue 95 for more details on the Forest Plan Amendment). Their 15-year implementation history gives us confidence that they will do so. Additionally, the Conservation Strategy was signed by State agencies and Federal land management agencies in December 2016 and is currently in place. See Issue 48 for more information about which habitat components, including the abundance of ungulates, will be monitored. The IGBST will continue demographic monitoring of the GYE grizzly bear population and the habitat criteria set forth in the 2016 Conservation Strategy; therefore, the IGBST would be able to detect if changes in vital rates occurred and evaluate whether they were a result of changes in habitat quality or quantity. Upon completion of a demographic review, the IGBST will provide the information to the YGCC, who will decide if modifications to the 2016 Conservation Strategy are necessary.

Issue 44—Some commenters requested clarity on the ''habitat standards'' in the 2016 Conservation Strategy, including: (1) When, how, and by whom the standards would be revised, and (2) additional information on the ''administrative and maintenance needs'' that allow exceptions to the standards. Commenters also worried that the plans for habitat management (as a means to reduce human-caused mortality) in the 2016 Conservation Strategy lacked specificity and timelines.

Response—The habitat standards in the 2016 Conservation Strategy will be in effect for the foreseeable future. Results of habitat monitoring, as set forth in the 2016 Conservation Strategy (YES 2016a, pp. 54–85), will be reported in the IGBST annual reports. Revisions to the Conservation Strategy would be based on the best available science, approved by the YGCC, and subject to public comment. If the IGBST detects changes to the population as a result of habitat loss or modification through their demographic monitoring of the population, the YGCC may determine that revisions to the Conservation Strategy are necessary to maintain a recovered grizzly bear population in the GYE. The Service will initiate a formal status review if there are any changes in Federal, State, or Tribal laws, rules, regulations, or management plans that depart significantly from the specifics of population or habitat management detailed in this rule and the Conservation Strategy and significantly increase the threat to the population. The 2016 Conservation Strategy details the application rules that outline conditions under which Federal projects are authorized to cause permanent changes to secure habitat and developed sites, including administrative and maintenance activities (YES 2016a, pp. 61–67). The habitat management standards detailed in the 2016 Conservation Strategy (YES 2016a, pp. 54–85) to reduce human-caused mortality have already been implemented through National Park Compendia (YNP 2014b, p. 18; GTNP and JDR 2016, p. 3) and the 2006 Forest Plan Amendment (USDA FS 2006b, entire).

Issue 45—We received several comments from both the public and peer-reviewers regarding use and development in secure habitat within the PCA including: (1) That increased development on lands surrounding the National Parks should be considered; and (2) the exceptions that allow changes to the 1998 baseline for secure habitat and developed sites for administrative and maintenance needs should either be limited or further clarified. In addition, public commenters suggested that: (1) Projects that temporarily change the amount of secure habitat should not be allowed; and (2) recurring low-level helicopter flights and temporary road construction should not be allowed during denning season.

Response—We agree that developed sites on lands surrounding National Parks should be considered, and have done so. Within the PCA, the number and capacity of developed sites on public lands both inside and outside of the National Parks will be maintained at 1998 levels, a level that was compatible with an increasing grizzly bear population (Harris *et al.* 2006, p. 48). In suitable habitat outside the PCA, food storage orders, large percentages of Wilderness Areas, WSAs, or IRAs, and outreach programs will prevent and address the mortality risk associated with developed sites on public lands. On private lands, we have no authority to limit developed sites and do not think this is necessary. Approximately 1.5 percent of lands inside the PCA and 9 percent of suitable habitat outside the PCA are privately owned. These small proportions, coupled with the extensive outreach and conflict prevention and response protocols in the State management plans, ensure private land development is not a threat to the GYE grizzly bear population now, or in the future. For more information, please see *Factor A,* above.

However, we disagree that temporary projects should not be allowed on public lands inside the PCA. In general, it is reasonable and biologically sound to provide management flexibility and discretion to land management agencies so they can fulfill their mandates of balancing and accommodating multiple uses (USFS) and providing for public recreation while conserving resources (NPS). These allowances for temporary changes to secure habitat were based on known levels of project activities occurring during the 1990s, a time during which the GYE grizzly bear population was known to be increasing (Harris *et al.* 2006, p. 48). There are no biological data to demonstrate that the temporary 1 percent level of secure

habitat disturbance in any subunit has had any detrimental effect on the grizzly bear population. Temporary changes in secure habitat may not exceed 3 years, can affect no more than 1 percent of the largest subunit size within that BMU, may occur in only one subunit at a time, and project roads will not be open to public use (YES 2016a, pp. 63–64). These temporal and spatial restrictions, as well as the requirement that all secure habitat be restored upon completion of a temporary project, mean there will be no permanent loss of secure habitat in any subunit.

There is no exception to the 1998 baseline regarding administrative use of roads that are closed to the public. All roads, even if only open for administrative purposes, are considered open roads and are included in the 1998 baseline (YES 2016a, p. 61). There is a very specific statement in the 2016 Conservation Strategy (YES 2016a, p. 64) that allows administrative use on existing routes for the purposes of power line/utility maintenance. These roads are not open to the public, have no obvious footprint, and are used very rarely. As such, we continue to conclude that allowing access for power line and utility maintenance is not a threat to the GYE grizzly bear.

For developed sites on public lands, expansion of existing administrative sites is allowed if these are ''deemed necessary for enhancement of public land management and other viable alternatives are not available'' (YES 2016a, p. 66). This does not allow new developed sites for administrative purposes, only expansion in capacity or acreage of existing administrative sites. In general, administrative sites are occupied by trained personnel of the National Forests or National Parks, contain strictly enforced requirements for securing attractants from grizzly bears, and prohibit most personnel from carrying firearms. As such, administrative sites do not pose the same level of risk to grizzly bear survival as sites occupied by the general public, so it is reasonable to allow some expansion of capacity at these existing sites.

The allowance for temporary projects that include low-level helicopter flights and temporary road construction during the grizzly bear denning season (December 1–February 28) is also biologically sound and reasonable. While no studies have been conducted documenting impacts of low-level helicopter flights on grizzly bears during the denning season, as discussed in the *Factor A—Snowmobiling* section above, even direct disturbance at den sites due to snowmobiles does not necessarily result in den abandonment or any detectable consequences to grizzly bears. Furthermore, of the 652 grizzly bear mortalities that occurred between 1975 and 2014, only 1 occurred between Dec. 1 and Feb. 28. This single mortality was a radio-collared, 20-year-old male that died in January from natural causes in YNP, most likely from maladies associated with old age. We have no information suggesting that low-level helicopter flights during the denning season may be a threat to the GYE grizzly bear population now or in the future.

Issue 46—Numerous public commenters expressed concern about the negative effects of existing, and potential future development of, roads and trails, and the species' ability to respond to these threats, including: Habitat loss and fragmentation, increased access by humans into species' habitat, reductions in forage, reductions in connectivity, and collision mortality. Commenters suggested that strict guidelines on development of roads and trails are necessary to protect the species and, without these guidelines, the species will not persist without the protections of the Act. Specifically, public commenters suggested: (1) Road densities should continue to be limited after delisting to avoid potential increases in bear mortality and in logging activity; and (2) the distinction between permanent and temporary roads should be clarified since only the density of permanent roads is limited in the proposed rule, even though temporary logging roads may have higher traffic.

Response—There are no mandatory standards pertaining to motorized route densities; instead, levels of motorized access are limited indirectly by the standard for secure habitat. Consequently, open motorized access road density (OMARD) and total motorized access route density (TMARD) levels have been maintained at or below 1998 levels for all 40 subunits within the GBRZ (GYA Grizzly Bear Habitat Modeling Team 2015, pp. 118–119). Looking forward, inside the PCA, there will be no net increase, from the 1998 baseline, in OMARD, TMARD, or the number and capacity of developed sites from the 1998 baseline. Although OMARD measures only the density of motorized routes (roads and trails) that are open to the public for 1 or more days during the non-denning season (March 1–November 30), TMARD measures the density of motorized routes open to the public and/or administrative personnel for 1 or more days during the non-denning season (YES 2016b, Appendix E).

A notable number of improvements in route density since 1998 have taken place on subunits that are partially or completely contained within the Gallatin National Forest. The documented decreases in motorized route density can be directly attributed to implementation of the 2006 Gallatin National Forest (NF) Travel Plan and reflects an overall goal to manage motorized access in a manner that allows for recovery of threatened species such as the grizzly bear. In areas of suitable habitat outside the PCA, we do not anticipate any significant increases in road densities because of other existing plans and designations (*e.g.,* the Gallatin NF Travel Plan, the Caribou-Targhee NF Travel Plan, Wilderness, WSA, and IRA designations, State Management Plans recommending road densities of less than 1 mi/mi^2, etc.). In fact, because of these other existing plans or designations, there have been 0.1 to 6.1 percent increases in secure, suitable habitat outside the PCA since 2008 (GYA Grizzly Bear Habitat Modeling Team 2015, pp. 102–103). In addition, 60 percent of suitable habitat outside of the PCA is protected from increases in motorized use and development through its designation as Wilderness, WSAs, or IRAs.

Temporary roads are extremely limited by the application rules described in the 2016 Conservation Strategy and associated National Park and National Forest management plans. See Issues 44 and 45 for additional information.

Issue 47—We received several public comments regarding discussion and treatment of stressors inside and outside of the PCA, including: (1) Questioning our scientific basis for allowing different management techniques within and outside the PCA and whether there is evidence of two distinct grizzly bear populations (one inside the PCA and one outside the PCA) warranting distinct management approaches; (2) claiming that it was ''disingenuous'' for us to state that ''suitable habitat outside the PCA provides additional ecological resiliency and habitat redundancy to allow the population to respond to environmental changes'' when the same habitat protections and monitoring do not exist outside of the PCA; (3) noting that habitat outside of the PCA has ''become a sink for human-caused mortalities;'' (4) questioning the presence of 500 development sites on the 5 National Forests in suitable habitat outside the PCA; (5) suggesting that we cannot rely on State plans to protect habitat outside of the PCA; (6) specifying that the Service must address

in the threats analysis that 40 percent of habitat outside of the PCA is not protected; (7) claiming that the Service is ''writing off'' 25 percent of independent females, since these females live outside the PCA in areas that will have inadequate habitat protections, which could result in mortality levels that exceed prescribed limits; and (8) suggesting that potential increased road development outside of the PCA will be associated with increased grizzly bear displacement, higher mortality, and lower fecundity. Additionally, commenters noted that if improved management has reduced mortality inside the PCA, management and protections should be similarly improved for habitats outside of the PCA and the same mortality limits and habitat protections apply in the entire DMA.

Response—The Service has applied a reserve design approach by designating, and providing differential levels of management and protection in, the PCA. The PCA, which is a subset of suitable habitat, contains approximately 75 percent of the females with cubs (the population's most important age and sex group) (Haroldson 2014a, *in litt.*) and will continue to serve as a source area for the rest of the GYE. Differential levels of management and protection are based on their relative level of importance. Within the PCA, comprehensive protections are in place via the objective and measurable habitat criteria concerning secure habitat, human site developments, and livestock allotments, which will be habitat requirements on public lands once this final rule becomes effective (YES 2016a, pp. 54–72). Outside of the PCA in suitable habitat, there are not specific protections in place for grizzly bears (other than food storage orders); however, the amount of permanently secure habitat provides them with the most important habitat protection possible for grizzly bear survival: Limited motorized access. Mortality limits apply throughout the entire DMA.

While there are not two distinct grizzly bear populations inside and outside of the PCA, the single GYE grizzly bear population experiences different growth rates in these areas. When the population was growing at 4 to 7 percent per year in the 1990s (Harris *et al.* 2006, p. 48), most of this growth occurred inside the PCA (Schwartz *et al.* 2006b, p. 64). Similarly, when the growth rate for the entire GYE slowed between 2002 and 2011, the PCA still experienced higher growth rates than adjacent areas outside the PCA (IGBST 2012, p. 34). These differences in population growth rate inside and outside of the PCA are a testament to the effectiveness of the differential management approach (varying levels of protection based on relative importance to grizzly bears) under the IGBC Guidelines that led to grizzly bear recovery in the GYE (USDA FS 2004, p. 19). Under the Guidelines, there were five different ''Management Situations'' identified throughout the PCA, each with its own management direction (USDA FS 1986, pp. 3–5). These Guidelines contained no direction for management outside the PCA so lands within the PCA were always managed differently than areas outside the PCA. Such flexible management promotes communication and tolerance for grizzly bear recovery, and the best available science demonstrates that the PCA contains the habitat necessary to serve as a source area for a healthy and long-term viable grizzly bear population, and will continue to do so post-delisting.

We maintain that suitable habitat outside the PCA provides additional ecological resiliency to the population. Unlike inside the PCA, there are areas of suitable habitat outside the PCA that are not currently occupied and that contain large stands of healthy whitebark pine (*e.g.,* the southern Wind River Range) and vast tracts of secure habitat due to Wilderness, WSA, or IRA designations. For example, 2,948 km^2 (1,138 mi^2) of the Wind River Range, including almost all of the high-elevation whitebark pine stands, are in designated Wilderness Areas.

Issue 48—We received several comments from the public concerned with the habitat monitoring. These comments included that: (1) We do not explain what indices will be used to monitor changes in habitat and why these indices are adequate indicators of habitat degradation; (2) we do not provide adequate assurances that we will employ sufficient monitoring, beyond tracking population size, to detect possible ''lag effects;'' (3) we do not specify who would measure and report on the four habitat criteria in Chapter 3 of the 2016 Conservation Strategy, when the information would be collected and reported, and to whom it would be reported; and (4) one commenter suggested that we review land management activities on public lands every 3 years.

Response—The 2016 Conservation Strategy commits the implementing agencies to intensive monitoring of all grizzly bear vital rates and the relationship of these vital rates to changes in major foods and levels and types of human activities in their habitat. Annual habitat monitoring will produce results on any changes in habitat values and key food production. Details on who is responsible for food and habitat monitoring are outlined in the 2016 Conservation Strategy (YES 2016b, Appendices D, E, and F) and are reported in the IGBST Annual Reports. Thus, the system in place will not rely on indirect measures of habitat values but will annually produce direct measures of habitat values.

The multiple indices used to monitor both bear foods and bear vital rates provide a dynamic and intensive data source that allows the agencies to respond in a timely manner to results that might indicate problems. The GYE monitoring system under the 2016 Conservation Strategy (YES 2016a, pp. 33–85) is one of the most detailed and comprehensive monitoring systems developed for any wildlife species. Specific habitat variables that will be monitored include: Amount and location of secure habitat, open motorized route densities, total motorized route densities, developed sites, relative abundance of ungulates, cutthroat trout abundance and use, grizzly bear use of army cutworm moth sites, whitebark pine abundance, and grizzly bear distribution and mortality. Since we will be monitoring a suite of demographic vital rates including survival of radio-collared bears, home range size, mortality of all bears from all causes in all areas, causes and locations of grizzly bear-human conflicts, body condition, and reproductive statistics like litter size, litter interval, generation time, and age of first reproduction, we are confident that we will be able to detect the consequences of significantly reduced habitat productivity soon enough to respond with changes to management approaches.

For the habitat components that are part of the 1998 baseline (*i.e.,* secure habitat, developed sites on public lands, and livestock allotments), we have *de facto* triggers and management responses. If there are any changes in these values that depart from the 1998 baseline, there are enforceable requirements to address these deviations. Further, if grizzly bear mortalities exceed the mortality limits in a given year due to changes in habitat or resources (*e.g.,* vehicle collision due to new road or management removal due to new livestock allotment), discretionary mortality would not be allowed, except for human safety. Therefore, the monitoring and adaptive management system described in the 2016 Conservation Strategy (YES 2016a, entire) ensures the maintenance of a recovered GYE grizzly bear population.

Finally, we are not able to commit to reviewing land management activities on public lands every 3 years. However, we do commit to monitoring secure habitat and motorized access route density, developed sites, livestock grazing, and grizzly bear foods according to the protocol outlined in the Conservation Strategy (YES 2016a, pp. 68–73).

Issue 49—Several commenters raised concerns with our use of the 1998 baseline for habitat management. Some commenters suggested that the 1998 baseline would be insufficient to protect grizzly bears (especially in the absence of the Act's protections and its associated section 9 ''take'' prohibitions, section 7 consultation, and citizen suit provisions, and the 1986 Interagency Grizzly Bear Guidelines under which conflict bears are managed). Other commenters questioned the validity, and subsequent sufficiency, of the 1998 baseline because: (1) 1998 does not actually represent a period of population growth since the population growth rate from 1988 to 1998 was overestimated (Pease and Mattson 1999); (2) it was calculated using a nonparametric Chao2 estimator instead of the current model-averaged Chao2 estimator; (3) it does not appropriately distinguish between the frequency of contact with humans and the lethality of these encounters with humans (*i.e.,* high use does not necessarily imply high risk to grizzly bears, and low use does not necessarily imply low risk to grizzly bears); and (4) if any lands burned during the 1988 fires, the habitat on those lands was thus not stable during the 1988 to 1998 period, as the Service claimed.

There were several comments regarding whether or not the 1998 habitat baseline has been maintained in the past or could be maintained into the future. Peer-reviewers and several commenters asked: (1) For additional detail on changes in habitat, roads, and developments from the past 40 years (especially since 1998), even if the amount of secure habitat has not changed, as these specifics could shed light on the feasibility and appropriateness of the 1998 baseline; and (2) whether agencies have been, and can remain, in compliance with the 1998 baseline; and, in particular, the three BMU subunits in the Targhee and Gallatin NF, which needed improvements in secure habitat in 2007. Some commenters expressed concern with the 2006 Gallatin Travel Management Plan implementation and questioned if it was approved; commenters expressed confusion as to ''why the Service is not enforcing the Gallatin NF to decommission motorized routes and develop sites to comply with the 1998 baselines as all other forests have done.''

A number of commenters presented alternatives to the 1998 baseline including: (1) Using current conditions for the baseline, since bears are recovered under current conditions; and (2) using the ''moving window analysis'' from Mace and Waller (1996), which recommends open motorized route densities, total motorized route densities, and core amounts of habitat for each BMU. A peer-reviewer suggested using a defining period of 1988 to 2005, unless there were unique habitat features that were stable between 1988 and 1998. And lastly, many commenters worried that negotiations around the 2016 Conservation Strategy have already changed the 1998 baseline, and we have not adjusted our explanation of secure habitat or threats analysis accordingly.

Response—The year 1998 was chosen because secure habitat and site developments had been roughly the same during the previous 10 years (USDA FS 2004, p. 27) and the population was increasing during these years (Eberhardt and Knight 1996, p. 419; Harris *et al.* 2006, p. 48). The selection of any other year between 1988 and 1998 would have resulted in approximately the same baseline values for roads and developed sites. We did not select baseline habitat values from years before 1988 because habitat improvements that occurred after the implementation of the IGBC (USDA FS 1986, pp. 6–21) would not have been reflected. Although we recognize that the frequency of human-grizzly bear encounters does not equate to the lethality of human-grizzly bear encounters, motorized access management is the most effective management tool for reducing grizzly bear mortality risk (Nielsen *et al.* 2006, p. 225; Schwartz *et al.* 2010, p. 661); see Issues 30, 40, 41, and 42. Additional measures to reduce the lethality of human-grizzly bear encounters include removing or securing attractants and providing education to modify human behavior/practices that contribute to conflict (YES 2016a, pp. 86–95). The 1998 baseline provides the same level of habitat protection whether the GYE grizzly bear is listed or not under the Act. The 1998 baseline refers to stability in the amount of secure habitat and number and capacity of developed sites to reduce human-bear conflicts and human-caused mortalities.

We recognize that the 1988 fires and other natural events may alter habitat, including the distribution and abundance of foods across the landscape, in the GYE. However, there is no evidence that fires detrimentally affect grizzly bears (see Issue 61). We agree that mortality risk is not static within secure habitat. Schwartz *et al.* (2010, p. 658) mapped grizzly bear mortality risk down to the 30-m (98-ft) pixel scale to identify areas where grizzly bear survival was greatest. While Schwartz *et al.* (2010, p. 661) found spatial variation in mortality risk, this fine-scale variation does not matter at the population level because it is accounted for in the sustainable mortality rates set by the IGBST. Regarding the comment that social and dietary changes since 1998 have resulted in increased exposure to human hazards despite no net increase in livestock allotments and human infrastructure, we note that increased exposure to human hazards in and of itself is not necessarily a problem. It becomes a problem when there are an unsustainable number of bears dying as a result of this increased risk and we feel confident the ecosystem-wide mortality limits and subsequent management responses to grizzly bear-human conflicts will adequately address any increased exposure to human hazards such that a recovered grizzly bear population is maintained within the GYE.

For a discussion on overestimation of population growth estimation and Pease and Mattson (1999), please refer to *Factor E,* above.

Habitat conditions relating to the habitat standards described in the 2016 Conservation Strategy (YES 2016a, pp. 54–85) have either remained stable or improved from the 1998 baseline levels of secure habitat, site developments, and livestock allotments. The Grizzly Bear Annual Habitat Monitoring Report includes changes and corrections to the 1998 baseline and is included in the IGBST Annual Reports. The 1998 baseline: (1) Was not developed to address specific projects such as oil and gas development or timber harvest; (2) does not contain threshold values for any of the major foods due to the natural annual variability in their abundance and distribution; and (3) attempted to establish realistic habitat standards that ensure adequate habitat security and minimum livestock conflicts within the PCA. Therefore, we consider the establishment of habitat thresholds for human population growth, food sources, and specific projects to be unrealistic and that the 1998 baseline will adequately address these issues through access management and limitations on site development.

As the commenters point out, the moving window analysis approach represents the best available science and is the method used for measuring route densities on public lands in the GYE. Motorized route densities and percentages of secure (''core'') habitat within the GYE are calculated using a suite of GIS geospatial tools that are packaged as the *Motorized Access Model.* Calculations for motorized route densities are based on a ''moving window analysis'' similar to that of Mace and Waller (1996, p. 1398), and include algorithms that have been improved since 1997 to more accurately calculate the total length of motorized routes per unit area. Mace and Waller (1996, p. 1395) determined that bears underutilized areas within 500 m (1,640 ft) from open roads with use levels greater than 10 vehicles per day. Based on this finding, secure (''core'') habitat is defined in the GYE as any contiguous area greater than 10 acres in size and more than 500 m (1,640 ft) from an open motorized access route during the non-denning period. Secure levels are expressed as the percentage of the subunit that meets this definition. Any road that is open to motorized traffic for at least 1 day or more during the non-denning season (regardless of vehicle use levels) detracts from secure habitat calculations. Furthermore, routes that are gated and closed to the public year round, but which may occasionally be accessed by management personnel for administrative purposes, also detract from secure habitat. In other words, open and gated motorized routes are buffered by 500 m (1,640 ft), and these buffered areas do not count toward secure habitat.

Although no specific standards are directly imposed on motorized route densities, road construction is significantly curtailed by imposing a no-net-decrease in secure habitat per bear management subunit inside the PCA. The commenter refers to the NCDE provision for core area amounts (68 percent/2,500 acres). It is true that *most* BMUs in the NCDE are managed to maintain a minimum of 68 percent secure habitat. This is also the case in the GYE. Secure habitat is maintained at or above 1998 baseline levels. All 40 subunits inside the GYE PCA, except for 3 subunits (Henrys Lake #1, Henrys Lake #2, and Madison #2), have secure levels exceeding 68 percent. More than half of the subunits ($n = 21$) have secure levels at or exceeding 90 percent, and 4 subunits are completely roadless with secure habitat levels at 100 percent. Throughout the PCA, approximately 87 percent (excluding major lakes) is deemed secure habitat. With the provision for no net loss in secure habitat, the 10-acre size restriction for secure habitat ensures that small isolated pockets of roadless areas are preserved. The deficient levels of secure habitat for the 3 subunits below 68 percent are mostly due to motorized routes on private lands, as well as the legal requirements that National Forest lands provide access to State and private lands, mining claims, and summer homes, as well as county, State, and Federal rights of way. Because of the disproportionate number of restrictions on these three subunits, little opportunity exists to further improve secure levels via Federal management practices beyond the improvements that have been implemented under the 2006 Gallatin NF Travel Management Plan.

The Gallatin NF Management Plan was approved in 2006 and has implemented the 1998 baseline. The three subunits identified by the 2007 Conservation Strategy that were in need of improvement were on the Targhee and Gallatin NFs, although the portions of these subunits that were identified as in need of improvement were within the Gallatin NF. The high road density values and subsequently low levels of secure habitat in these subunits is primarily due to motorized access on private land (USFWS 2007*a,* pp. 145–153). Managers have made improvements in these areas and attained full implementation of the 2006 Gallatin NF Travel Management Plan. These three subunits have shown on average a 7.5 percent increase in secure habitat, and these improved levels will serve as the new baseline for these three subunits (YES 2016b, Appendix E). These levels of secure habitat will continue to support a stable to increasing population of grizzly bears. Revisions to the draft 2016 Conservation Strategy did not change the 1998 baseline.

Issue 50—Some commenters expressed that there is sufficient connectivity between grizzly bear populations and that grizzly bears are making ample use of connectivity corridors, as evidenced by recent sightings of grizzly bears in new territory surrounding the GYE, in the Big Hole Valley, on ''the prairie lands of eastern Montana,'' and between the GYE and the Northern Rockies population. Conversely, many comments from the public and peer-reviewers suggested that our discussion of connectivity of grizzly bear habitat and populations in the proposed rule and the 2016 Conservation Strategy was inadequate and required additional detail; commenters and peer-reviewers thought connectivity was essential for long-term viability of the population and species and that current levels of connectivity are inadequate. Calling the GYE grizzly bear population an ''island population,'' commenters and peer-reviewers warned of the deleterious genetic effects, demographic concerns, environmental threats, and catastrophic events that could greatly diminish or eliminate the GYE population without sufficient natural or facilitated improvements in its demographic connectivity to other populations. Commenters suggested that we contradicted ourselves by saying that connectivity is both ''vital and unnecessary.''

Commenters suggested several remaining threats to connectivity warrant further discussion in the rule, including: (1) The 150 miles of farmland and roads that separate GYE grizzly bears from their northern neighbors; (2) proposed hunting (especially along NP boundaries), combined with high mortality rates (as much as 47 percent) outside the DMA could preclude future connectivity; and (3) large-scale and long-term effects of road construction, like fragmentation, can jeopardize connectivity. Peer-reviewers asked us to explain the relevance of food storage orders to the issue of connectivity and to more fully address remaining barriers to movement, such as topography or manmade structures, including a suggestion to provide scientific evidence of grizzly bear use of crossing structures to strengthen our promotion of these structures as a management tool.

Response—We continue to be encouraged by the expansion of grizzly bears into the area between the NCDE and the GYE; however, we have not yet documented connectivity between the ecosystems and do not know the origination of the bear in the Big Hole Valley. Connectivity is relevant to this rulemaking only to the extent that it impacts the GYE DPS. To that extent, connectivity or lack thereof has the potential to impact this population's genetic fitness. As such, this issue is discussed and addressed in our five-factor analysis (see *Factor E,* above) and in the 2016 Conservation Strategy (YES 2016a, pp. 82–85). The Service has considered population viability in considerable depth (Boyce *et al.* 2001, p. 2). Boyce *et al.* (2001, p. 1) concluded that the available data ''provide optimistic projections of the likelihood of persistence for grizzly bears in the GYE; a 99.2 percent probability that the GYE grizzly bear population will persist for 100 years.'' Please see Issue 27 for further discussion about population

viability analysis for the GYE population by Boyce *et al.* (2001).

Due to the habitat protections, population standards, mortality control, outreach efforts, and the adaptive management approach described in the 2016 Conservation Strategy, we conclude that isolation is not a threat to the GYE grizzly bear population and, therefore, does not preclude delisting. Based on estimated grizzly bear distribution in the NCDE (Costello *et al.* 2016, p. 18) and in the GYE (using the techniques described by Bjornlie *et al.* 2014a, p. 183–184, available at *https://www.sciencebase.gov/catalog/folder/52fe7f75e4b0354fef6de4f0*) as of 2014, the two populations are now only 71 miles apart. In addition, there have been multiple confirmed sightings outside of these distributions between the two ecosystems, such as in the Upper Big Hole last year. MFWP has indicated through their hunting season regulation framework and their Grizzly Bear Management Plan for Southwestern Montana that connectivity will be considered when relocating grizzly bears and in their setting of hunting quotas in potential connectivity corridors (MFWP 2013, p. 9; MFWP 2016, pp. 4–5). Please see Issue 96 for discussion of our assessment of potential genetic effects as a result of the GYE being an isolated population.

We have added a discussion of catastrophic events to this rule under *Factor E.* Although we acknowledge that connectivity is desirable for the long-term genetic health of the GYE grizzly bear population, at this time genetic health is not a concern for this population (see *Genetic Health* section of this rule). Connectivity will be facilitated through highway planning and food storage orders on public lands (YES 2016a, pp. 82–85; see Issue 51 for further discussion). Grizzly bears have been documented to use crossing structures in Alberta, with a preference for structures that were ''high, wide and short in length'' (Clevenger and Waltho 2005, p. 453; Sawaya *et al.* 2014, p. 7). Distance to cover was also positively correlated with grizzly bear use, whereas human activity (*i.e.,* traffic noise) was negatively correlated with use (Clevenger and Waltho 2005, p. 459).

Issue 51—Commenters stated that the 2016 Conservation Strategy did not cite any methods for modeling connectivity and that plans for monitoring connectivity are vague or weak. Several peer-reviewers suggested that: (1) Monitoring and collecting genetic samples (*e.g.,* through mandatory registration of bears hunted in the GYE or environmental DNA techniques), especially outside the DMA, could help detect movements between grizzly bear populations; and (2) the ''step-selection function'' method in Thurfjell *et al.* (2014) should be used to ''model habitat attributes that facilitate movement and connectivity.''

Response—Federal and State agencies will continue to monitor grizzly bear activity in potential connectivity areas between the GYE and the NCDE and between the GYE and the Bitterroot to document natural connectivity. Monitoring will occur using both radio telemetry and with the collection of genetic samples from all captured or dead bears to document possible gene flow between the two ecosystems. Please see the *Genetic Health* section of this final rule for further discussion on genetic monitoring to detect connectivity. Environmental DNA (eDNA) is used to detect the presence of difficult to detect species by collecting genetic samples present in their environment and has typically been used for aquatic or semi-aquatic species (Schultz and Lance 2015, p. 2). Methods to use eDNA for terrestrial species are still being developed and are not currently applicable to grizzly bears. Although detection may be possible at drinking water sources, current techniques are limited to small, slow-moving bodies of water (Rodgers and Mock 2015, p. 695). Current methods detect only species' presence and would not provide necessary information to determine the most likely population from which it originated. The IGBST is currently working on modeling to identify potential connectivity corridors between the NCDE and the GYE. Please visit our Web page for maps of the recovery zones and current known distributions, as available (*https://www.fws.gov/mountain-prairie/es/grizzlyBear.php*).

Issue 52—Several commenters also suggested methods to facilitate connectivity to other ecosystems or potential habitat areas prior to, or concurrent with, delisting, including: (1) Creating demographic connectivity areas, similar to the draft NCDE Conservation Strategy; (2) implementing the same habitat standards in connectivity areas as those that apply inside the PCA, designating connectivity corridors as wilderness areas, and building ''wildlife bridges'' to allow bears to cross highways; (3) reducing the DPS boundaries to match those of the DMA; (4) protecting forests with large roadless tracts; and (5) working with the conservation group Yellowstone to Yukon.

Response—All Federal and State agencies are committed to facilitating connectivity (YES 2016a, pp. 82–83). Although the structure of the GYE boundaries are different than those proposed in the draft NCDE Conservation Strategy, the DMA boundary extends all the way to the DPS boundary in sections to the west and north to facilitate connectivity between the GYE and both the NCDE and the Bitterroot ecosystem. Connectivity will be managed for in highway planning (YES 2016a, p. 83). Food storage orders are already in place on the majority of USFS lands to facilitate connectivity by minimizing human-grizzly bear conflicts (YES 2016a, pp. 84–85). Lastly, the Service currently partners with nongovernmental organizations who work to conserve important habitat linkage areas, including Vital Grounds and Yellowstone to Yukon.

Issue 53—Some peer-reviewers and commenters stated that we either did not have or did not share effective, detailed Service or State plans for facilitating connectivity between the 6 grizzly bear recovery zones in the lower 48 States. Specifically, they expressed concerns that State management plans and regulations will discourage movement of grizzly bears and prevent necessary connectivity, including that: (1) Recolonization of the Bitterroot Ecosystem will be prohibited by a combination of inadequate plans for limiting mortality in linkage zones between the GYE and the Bitterroot Ecosystem (*i.e.,* the Upper Snake River Region) and Idaho's management plan's prohibition on movement of grizzly bears into new areas; (2) the proposed rule, the Tri-State MOA, and the 2016 Conservation Strategy do not include strong enough commitments and clear partnerships that will ensure grizzly bear habitat connectivity (especially as considerations in any new road construction or highway improvement projects); (3) Idaho's and Wyoming's State plans do not discuss connectivity at all or will actively prevent the successful recolonization of unoccupied historical range because of potential for conflict (*e.g.,* Wyoming and southern Wind River range); and (4) all of the State plans will ''actively discourage,'' ''limit,'' ''persecute,'' or remove bears outside the DMA because the States have publicly shared that the Service cannot and should not ''impose additional requirements as to connectivity for delisting the GYE DPS, where connectivity and genetic exchange do not threaten the populations.''

For Montana, public commenters were concerned that the State's: (1) Plan and regulations are noncommittal or unclear on the subject of connectivity,

and regulations fail to protect bears moving between the GYE and the NCDE because they (a) only promise to manage discretionary mortality and establish ''attractant storage rules;'' (b) requested removal of any language committing to effective management of mortality to facilitate connectivity, and the plan does not declare certain areas unsuitable for hunting due to importance for connectivity; (2) actions have not met the Service's apparent requirement in the proposed rule to effectively manage discretionary mortality in linkage zones; and (3) the plan does not contain language akin to that in the NCDE Conservation Strategy that discusses conflict management in the linkage zone between the GYE and the NCDE.

Other commenters suggested that State plans must manage for connectivity rather than managing toward a minimum population level and should have comprehensive management plans, not just for the GYE, that integrate all of the grizzly bear populations in their State and discuss how to facilitate connectivity between them. Overall, commenters expressed that States must provide more explicit and robust commitments to ensuring connectivity for delisting to be justified and that the final rule must ''commit to connectivity and coordinated management.'' Without these commitments, commenters asserted that the delisting would violate Service regulations, the National Forest Management Act, NEPA, the APA, and § 219.9 of the 2012 Forest Planning Rule.

Conversely, the States commented that: (1) Their discussions of connectivity in plans and regulations were sufficient to ensure the continued recovery of the GYE grizzly bear population to which one public commenter agreed with Montana; (2) the proposed rule may be too prescriptive on the subject of connectivity and movement between ecosystems; and (3) the Service should remove references to bear occupancy outside the DMA in the recovery supplement because the best available science indicates genetic connectivity is not a threat to the GYE population and the recovery criteria ''are conservative in recognition of the GYE DPS' relative isolation.''

Response—While connectivity among populations may be desirable, the Act does not require it for recovery or delisting. The 1993 Recovery Plan did not require connectivity for recovery of individual grizzly bear populations, and the Recovery Plan indicated the Service's intention to delist distinct populations as they met recovery goals (USFWS 1993, pp. ii, 33–34). In this final rule, we are designating and delisting the GYE population as a DPS. As stated in the proposed rule, based on the best available scientific data about grizzly bear locations and movements, the GYE grizzly bear population and other remaining grizzly bear populations are markedly, physically separated from each other. The GYE grizzly bear population meets the criterion of discreteness and significance criteria under our DPS Policy (see Issues 112, 113, 114, and 115, and the *Distinct Vertebrate Population Segment Policy Overview, Past Practice and History of Using DPSs,* and *Distinct Vertebrate Population Segment Analysis* sections of this final rule). Recovery of a DPS does not need to rely on genetic augmentation, whether natural or human assisted.

As stated in the proposed rule, connectivity/linkage, while desirable, is not required to maintain the GYE DPS. Published information indicates the genetic variability and viability of the GYE DPS is strong, and lack of connectivity is not a threat to the existence of the GYE DPS (in their entirety: Kamath *et al.* 2015; Luikart *et al.* 2010). Based on our analysis of the best available science (81 FR 13174, 13184, 13201, March 11, 2016; YES 2016a, pp. 51–52), we conclude that genetic concerns are not a threat to the GYE DPS and that bear occupancy, or lack thereof, in peripheral areas is not biologically necessary to the GYE DPS. In addition, as discussed in the *Demographic Recovery Criteria* section of this final rule and the 2016 Conservation Strategy (YES 2016a, pp. 34–37), we have applied conservative recovery and demographic monitoring criteria for the GYE population in recognition of its relative isolation.

For Recovery Zones outside the GYE DPS, the Act's protections will continue. The 2016 Conservation Strategy describes actions for habitat connectivity. Although connectivity with other Recovery Zones is not required for recovery or delisting of the GYE DPS, the 2016 Conservation Strategy and Montana's State management plan include a long-term goal of allowing grizzly bear populations in southwestern and western Montana to reconnect through the maintenance of non-conflict grizzly bears in areas between the ecosystems. The State of Montana has indicated that, while discretionary mortality may occur, the State will manage discretionary mortality to retain the opportunity for natural movements of bears between ecosystems. Grizzly bears have recently been documented in the Elkhorn Mountains, near Butte, Mill Creek, near Avon, and in the Big Hole, demonstrating that bears are moving into the area between the GYE and the NCDE and that natural connectivity is likely forthcoming; however, only the grizzly bears from near Butte and Mill Creek were confirmed as originating from the NCDE, and the ecosystem of origination for the other bears is unknown (pers. comm., M Haroldson). Montana's approved hunting regulations incorporate areas outside the DMA into hunting districts, and apply a quota to the whole hunting district based on the portion of the district within the DMA. This approach will better allow bears to occupy suitable habitat outside the DMA.

Although the Idaho Management Plan does not allow translocation of bears from the PCA to unoccupied areas within Idaho, it does allow for natural expansion into areas that are biologically suitable and socially acceptable. While the Wyoming Management Plan discourages occupation of areas outside of the DMA that are prone to conflict, it does not discourage occupancy of any sort as is implied by reviewer comment. The DMA was developed as an area within the GYE DPS to maintain consistent monitoring while providing large-scale suitable habitat sufficient in size to maintain a recovered grizzly bear population in perpetuity. However, this does not imply that bears cannot occur outside the DMA (as they currently do now) or into the future.

Issue 54—Public commenters and peer-reviewers expressed concerns with the adequacy of our discussion of livestock allotments in the proposed rule. Commenters suggested that livestock allotments remain a threat because: (1) They reduce connectivity since they contribute to habitat fragmentation, create a barrier to grizzly bear movements, and cause mortality sinks (including the U.S. Sheep Experiment Station); and (2) livestock allotments still cause a large proportion of grizzly bear mortality. A peer-reviewer suggested that changing environmental conditions could alter the conflict dynamics between grizzly bears and livestock allotments.

Commenters explained that the Service and its partners lack sufficient plans that will effectively ameliorate the threats from livestock allotments because: (1) Phasing out of livestock allotments is not, and has not been, an effective measure to reduce conflicts with wildlife; (2) there are currently no requirements to securely store or remove attractants, including livestock carcasses and feed, on private lands in the PCA; (3) current methods for

managing bears to limit livestock predation have failed since there were more conflicts with livestock in 2015 than at any point in the past 100 years, and there have been more than 500 confirmed livestock deaths since 1995; and (4) allowing private interests to control the phase-out of allotments may violate section 7 of the Act and other laws. Peer-reviewers also provided comments as to the inadequacy of plans to ameliorate threats from livestock allotments including that: (1) We do not have a plan to manage for the potential to have an increase in impacts from livestock allotments on grizzly bears; and (2) our proposed rule does not specify the total number of cattle we will allow on limited acreage of cattle allotments.

Commenters suggested methods to more effectively ameliorate the threats from livestock allotments and reduce conflict with livestock, including: (1) Conducting NEPA examination of all grazing allotments on public land and section 7 consultations before issuing any livestock allotment permits; (2) removing the livestock instead of the bear in cases of repeated conflicts; (3) encouraging landowners who have livestock allotment permits on Federal land to accept grizzly bear depredation of livestock, rather than expect retaliatory action towards grizzly bears; (4) instead of delisting, increasing support for programs that compensate landowners for livestock losses in place of retaliatory killing of grizzly bears; (5) requiring that livestock permits contain nonlethal conflict prevention measures before grizzly bear removal can occur; (6) including stronger, perhaps mandatory, language on livestock allotment phase-out, especially, according to one peer-reviewer, where conflicts are common, and including commitments to work with third parties to buy out allotments; (7) withdrawing most or all grazing rights on NF Land; and (8) removing leases from public lands that are ''edge areas'' important for connectivity or from all grizzly bear habitat. In addition, while some commenters suggested that the U.S. Sheep Experiment Station needs to be closed, others suggest that it has effectively used such nonlethal techniques to protect sheep from grizzly bears.

Conversely, some commenters worried about heightened negative impacts to ranchers if management of livestock allotments is made more stringent because compensation for relinquishing allotments is insufficient to cover the lost revenue to those ranchers. These commenters also suggested that the impact to livestock growers as a result of closing livestock allotments is disproportionate to the threat that these allotments pose, arguing that livestock allotments (especially sheep) are a comparatively small source of grizzly bear mortality (*e.g.,* approximately 5 and 34 percent from sheep and cattle conflicts, respectively). One commenter requested that the Service disclose the economic loss from the elimination of livestock allotments and collect more data on depredation of livestock. Commenters emphasized the problem that there are currently too many bears in the GYE, creating unsustainable predation pressure on the ranching industry. They suggested that delisting will increase the management flexibility of livestock owners and will provide needed tools for producers to protect livestock.

Response—We have thoroughly analyzed the issue of *Factor A, The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* and conclude that livestock allotments are not a threat to the GYE population now or in the foreseeable future. See Issue 40 for additional information.

Livestock permits are regulated through National Forest Land Management Plans, Livestock Grazing Permits, and/or Annual Operating Instructions. The USFS controls the number of permits and allotments, herd size, and season of use. In addition, permits contain carcass disposal requirements and enforce USFS food storage orders, which include livestock feed (for more details on food storage orders see YES 2016a, pp. 84–85). Existing permits within grizzly bear habitat, either under a programmatic review or for each allotment, have undergone section 7 analysis and any significant changes to these plans (*i.e.,* changes in herd numbers) post-delisting will be subject to a NEPA analysis. Coordination will occur with State wildlife management agencies to apply the conflict bear standards, including measures to prevent conflicts (YES 2016a, pp. 86–91). The IGBST identifies areas of concentrated conflicts to enable managers to focus subsequent efforts to prevent grizzly bear-human conflicts. All three State management plans contain direction on reducing grizzly bear-livestock conflicts and cooperating with private landowners to reach this goal (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 15–16; MFWP 2013, pp. 51–53; WGFD 2016, pp. 22–23).

Federal and State management agencies emphasize preventative measures and nonlethal techniques whenever possible (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 15–16; MFWP 2016, pp. 51–53; WGFD 2005, pp. 21–26). Inside the PCA, numerous sheep allotments have been retired or relocated to other, less-conflict-prone areas to accommodate grizzly bears (USDA FS 2006a, p. 170). As of 2006, there is only one remaining active sheep allotment inside the PCA (USDA FS 2006a, p. 168). Management removal will be used only as a last resort inside the PCA. The respective State wildlife agency's grizzly bear management plan will guide management of grizzly bear conflicts with livestock grazing on public lands outside of the PCA. Thus, removals as a result of these conflicts will remain within the sustainable mortality limits established in the 2016 Conservation Strategy. As such, this source of mortality will not threaten the GYE grizzly bear population.

The Service must make its decisions based on the best available scientific data. Therefore, we focus on whether or not grizzly bear mortalities resulting from conflicts with livestock affect the overall population trajectory. Grizzly bear mortalities associated with livestock depredations have mostly been eliminated within the PCA as most livestock allotments have been closed or retired. However, as the grizzly bear population expands beyond the PCA and beyond the DMA where livestock allotments remain, mortalities have again increased as a result of this range expansion. Mortality rates will remain within the biologically sustainable mortality rates in the demographic recovery criteria and the 2016 Conservation Strategy (see Issues 19 and 66). The Service has established conflict bear guidelines that are strategic in nature and provide managers with a framework to assess conflicts on a case-by-case basis. Grizzly bears depredating on lawfully present livestock on public lands may or may not be removed from the population, depending on several factors such as location of the conflict, severity of the incident, age and sex of the bear, and conflict history of the bear (YES 2016a, Chapter 4). While not required by the Act, State, Tribal, and Federal managers will continue to use a combination of management options in order to reduce grizzly bear-human conflicts, including nonlethal forms (Bangs *et al.* 2006, entire). However, these methods are effective in only some circumstances, and no single tool is a cure for every problem. Lethal control will still be required in many circumstances. Lethal control used in combination with nonlethal methods can improve the overall effectiveness of

both management options (Bangs *et al.* 2006, p. 8; Breitenmoser *et al.* 2005, p. 70).

Some commenters thought we needed stronger language making the phase-out of livestock allotments necessary. The Service has established a management system in the 2016 Conservation Strategy (YES 2016a, pp. 67–68, 72–73) that balances livestock grazing on public lands with the needs of grizzly bears. The vast majority of public lands in grizzly bear habitat in the GYE are managed with no livestock grazing. There is no livestock grazing on any of the National Parks in the GYE; the last livestock allotment in GTNP was closed in 2006. While livestock grazing allotments are a legitimate use of some public lands, we recognize that such grazing, especially sheep grazing, can lead to some grizzly bear mortality. In light of this understanding, and past management experience, the Service endorses an approach that includes minimizing livestock allotments with recurring conflicts.

The USFS's multiple-use mandate guides management to maintain a healthy forest while providing opportunities for wildlife and goods and services, such as livestock forage. Therefore, the USFS focuses on whether or not grizzly bear mortalities resulting from conflicts with livestock affect recovery of the population. The USFS has stated that, ''Inside the PCA, no new active commercial livestock grazing allotments would be created and there would be no increases in permitted sheep AMs from the identified 1998 baseline. Existing sheep allotments would be monitored, evaluated, and phased out as opportunities arise with willing permittees. Inside the PCA, cattle allotments or portions of cattle allotments with recurring conflicts that cannot be resolved through modification of grazing practices may be retired as opportunities arise with willing permittees. Outside the PCA in areas identified in State management plans as biologically suitable and socially acceptable for grizzly bear occupancy, livestock allotments or portions of allotments with recurring conflicts that cannot be resolved through modification of grazing practices may be retired as opportunities arise with willing permittees'' (USDA FA 2006a, pp. 36–37).

We conclude that this approach to livestock grazing is a logical and responsive way to manage grizzly bear-livestock conflicts. In some cases, the offer of financial incentives through nongovernmental organizations has been successful in retiring sheep allotments on public lands with willing participants (Gunther *et al.* 2004, p. 20). As explained in the proposed rule, as of 2014, there was only one active sheep allotment within the PCA, on the Caribou-Targhee NF. Because research has shown that grizzly bears and cattle are more likely to coexist without conflict than grizzly bears and sheep, the phasing out of cattle allotments inside the PCA will occur only when there are recurring, irresolvable conflicts on these allotments or if willing permittees volunteer to waive their permits back to the government (Knight and Judd 1983, p. 189; Anderson *et al.* 2002, pp. 254–255). Because there will continue to be no net increase in cattle or sheep allotments allowed on public lands inside the PCA, we do not expect that livestock allotments inside the PCA will constitute a threat to the GYE grizzly bear DPS now or in the future. Programs that compensate owners for livestock losses will continue in Idaho, Montana, and Wyoming regardless of the listing status of the grizzly bear.

The Final EIS for the Forest Plan Amendment for Grizzly Bear Habitat Conservation for the Greater Yellowstone Area National Forests includes an analysis of the potential economic impacts of implementing the 2007 Conservation Strategy, including the strategy surrounding livestock allotments (USDA FS 2006a, pp. 242–254). This Final EIS concludes that the negative economic impacts of implementing the 2007 Conservation Strategy would be minimal to livestock operators and do not outweigh the positive effects to grizzly bears (USDA FS 2006a, pp. 251–252).

Lastly, we disagree that the U.S. Sheep Experiment Station needs to be closed in order to conserve grizzly bears. The Station is located 6 miles north of Dubois, Idaho, and is 113 km^2 (70 mi^2) in size, and undertakes extensive efforts to prevent grizzly bear-livestock conflicts, including: Modifying the grazing schedule and/or movements; implementing good husbandry practices to keep the animals healthy; using full-time sheepherders, working dogs, and guard dogs on rangelands; limiting evening bedding areas; removal of lame livestock; minimization of unnatural attractants (*i.e.,* using bear-resistant containers); annual education of Sheep Station employees and herders on grizzly bear identification and conflict reduction; and reporting guidelines for all grizzly bear sightings and encounters. As a result, the Sheep Experiment Station has experienced no conflicts, management removals, or livestock losses from 2002 to 2014 (Mickelsen 2016, *in litt.*).

Issue 55—Several commenters stated that we inaccurately characterized the extent of present and future oil, gas, and mineral leasing in grizzly bear habitat because: (1) We incorrectly state that there are no oil and gas leases inside the PCA as of 1998 when the USFS data shows 9 parcels under lease; (2) there are 1,643 active leases in suitable grizzly bear habitat and the USFS has never denied a development request once a lease is granted; (3) 28 mines will be able to be developed if grizzly bears are delisted; (4) we do not acknowledge the Crevice and Emigrant Mines, two operations in the process of development, in the proposed rule; (5) Lucky Minerals, a Canadian mining company, is planning a mining operation less than 20 mi (32 km) from YNP that will lead to acid mine drainage; and (6) the Montanore Mine in the Cabinet Mountains Wilderness, and other hard rock mines, are affecting important grizzly bear habitat. A peer-reviewer also mentioned that 4 percent of suitable habitat inside, and 19 percent of suitable habitat outside, the PCA (but inside the DMA) allows for surface occupancy and that impacts of such occupancy can extend beyond the footprint itself.

Commenters suggested that these oil, gas, and mineral activities, especially those adjacent to USFS lands, will affect grizzly bear habitat and lead to population declines post delisting, since: (1) Mitigation is voluntary; (2) NEPA will be inadequate to ''curb harmful activities;'' (3) the 1872 General Mining Law could restrain abilities to limit any new mining developments; (4) areas associated with oil and gas boom towns have an increased incidence of poaching (Berger and Daneke 1988); (5) the effects of honoring existing oil, gas, and other mineral leases are unclear; (6) denning bears, particularly females, have decreased fitness when disturbed by forest cutting, mining, oil and gas exploration, and human recreation; and (7) delisting will ''lift'' restrictions on oil, gas, and mineral leases in the GYE. A peer-reviewer also noted that it is unclear what actions land managers will take to mitigate for potential impacts from existing leases given the current language that land managers are ''striving'' to meet the application rules for changes to secure habitat.

Commenters requested additional plans and assurances to adequately explain amelioration of this threat such as: (1) More explicit plans for monitoring and mitigation; (2) complete removal, or at a minimum, commitments for no new oil, gas, or mining projects within the PCA after delisting; and (3) clarity on whether

new oil, gas, or mineral projects that occur within the PCA would be required to mitigate for impacts on secure habitat by replacing the loss with intact secure habitat of similar habitat quality. A peer-reviewer also requested ''additional clarification on the number of leases, the location and area of leases, and possible range of effects of these leases.''

Response—We have thoroughly analyzed the issue of *Factor A, The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* and conclude that extractive industries (*e.g.,* oil, gas, mining) are not a threat to the GYE grizzly bear population now or in the foreseeable future. The proposed rule accurately stated that there are no active oil and gas leases inside the PCA (81 FR 13196, March 11, 2016); however, in 2016 there were eight suspended oil and gas leases in or partially in the PCA. In addition, there are 50 leases in, or partially in, suitable habitat (2 are phosphate leases on the Caribou-Targhee and the rest are oil and gas leases). That is similar to or fewer than the number analyzed as part of the 2007 Conservation Strategy.

The potential for future increases in oil and gas leasing inside the PCA on National Forest lands is guided by the 2016 Conservation Strategy and its limitations on road density and development (YES 2016a, pp. 60–72). We do not anticipate a dramatic increase in resource extraction outside of the PCA either due to the quantity of National Forest land designated as Wilderness (6,799 km^2 (2,625 mi^2)), WSA (708 km^2 (273 mi^2)), or IRA (6,179 km^2 (2,386 mi^2)). Approximately 80 percent of all suitable habitat on National Forest lands outside the PCA falls into one of these categories. There are also moderate to low potentials for both oil and gas occurrence and development throughout most of the six GYE National Forests, with the exception of the Bridger-Teton National Forest (USDA FS 2006a, pp. 210–213). Even with the high potential for occurrence and development in the Bridger-Teton, only 13 active oil and gas wells are currently inside that National Forest and none are within the DMA. In fact, there are no active oil and gas wells in suitable habitat. There has never been any high-density oil and gas development in suitable grizzly bear habitat in the GYE. The 1998 baseline for habitat standards was chosen as a level of development that existed during a period of robust grizzly bear population growth. We acknowledge that effects of not only mineral development but administrative and recreation uses can extend beyond the footprint of the activity, but those effects have been considered as part of our analysis. Additionally, any such proposed projects on Federal land would be subject to environmental review under the NEPA process, which requires Federal agencies to consider environmental effects that include, among others, impacts to wildlife, including possible mitigation measures.

The proposed rule (81 FR 13196, March 11, 2017) accurately stated that, ''Additionally, 1,354 preexisting mining claims were located in 10 of the subunits inside the PCA (YES 2016b, Appendix E), but only 28 of these mining claims had operating plans. These operating plans are included in the 1998 developed site baseline.'' Activity on these 28 claims in both the PCA and suitable habitat range from small intermittent operations to 2 large mines producing platinum and palladium on the Custer-Gallatin National Forests. While claimants under the 1872 General Mining Law have a right to explore for and develop valuable mineral deposits on their claims, the USFS develops appropriate mitigations for these claims through analysis and the NEPA process (42 U.S.C. 4321–4347.1970, as amended). Please see the 2016 Conservation Strategy (YES 2016a, pp. 62–67) for additional details on required mitigation. The proposed Montanore Mine in the Cabinet Mountains is outside the scope of this rulemaking because it is not located in the GYE. Mitigation of mineral activity on BLM-managed lands requires NEPA, and the effects analysis helps determine the appropriate mitigation.

State agencies are authorized to permit and determine appropriate mitigation for operations on private and State lands. The Wyoming Department of Environmental Quality's Land Quality Division (LQD) permits and licenses to ''ensure that land disturbances resulting from mining are minimal, and that affected areas are properly restored once mining is complete'' (Wyoming Department of Environment Quality–Land Quality Division 2017). The Idaho Department of Lands permits surface and placer mining operations from beginning through reclamation. The Montana Department of Environmental Quality permits and licenses mining in Montana. The Idaho and Wyoming Oil and Gas Conservation Commissions and the Montana Board of Oil and Gas Conservation are the agencies authorized to permit and regulate oil and gas wells. The State agencies also have a role in permitting on the Federal lands. Operators proposing projects to develop federally owned minerals have to get both Federal approvals and the appropriate State permits, licenses, or approvals. While it varies by State, additional State agencies may be responsible for a variety of resources such as water discharge permits or air quality permits whether the proposed operations are on Federal or non-Federal lands.

The level of exploration and development on Federal lands has remained relatively constant over approximately 20 years. Mineralized areas with a history of exploration and development particularly occur on the Custer-Gallatin NF. Activity has remained within the level described in the 1998 developed site list. To the fullest extent of its regulatory authority, the USFS will minimize effects on grizzly bear habitat from those activities based in statutory rights (*e.g.,* the 1872 General Mining Law). Mitigation requirements will follow those outlined in the 2016 Conservation Strategy, and described below (YES 2016a, pp. 62–63). The 2016 Conservation Strategy and this final rule do not preclude future mineral development, but have set in place mitigations that will allow grizzly bear populations to be maintained.

Under the 2016 Conservation Strategy, any new oil, gas, or mineral project will be approved only if it conforms to secure habitat and developed site standards (YES 2016a, pp. 54–85). For instance, any oil, gas, or mineral project that permanently reduces the amount of secure habitat will have to provide replacement secure habitat of similar habitat quality (based on our scientific understanding of grizzly bear habitat). Any change in developed sites will require mitigation equivalent to the type and extent of the impact, and such mitigation must be in place prior to project initiation or be provided concurrently with project development as an integral part of the project plan (YES 2016a, pp. 54–85). For projects that temporarily change the amount of secure habitat, only one project is allowed in any subunit at any time (YES 2016a, pp. 54–85). Mitigation of any project will occur within the same subunit and will be proportional to the type and extent of the project (YES 2016a, pp. 54–85). In conclusion, because any new mineral or energy development will continue to be approved only if it conforms to the secure habitat and developed site standards set forth in the 2016 Conservation Strategy, we conclude that such development inside the PCA will not constitute a threat to the GYE grizzly

bear DPS now or in the foreseeable future.

Issue 56—We received comments from both the public and peer-reviewers expressing concerns regarding our discussion of snowmobiling. Specifically, these commenters asserted that a lack of evidence of impacts does not equate to a conclusion of no impact from snowmobiles. Additionally, they recommended that monitoring alone is insufficient management and that active management programs should be initiated to mitigate the potential impacts of snowmobiling (*e.g.,* minimizing overlap between snowmobiles and denning habitat and/or limiting snowmobiles after den emergence dates). Lastly, public comments suggested that we did not adequately consider impacts from activities associated with snowmobiling, such as the use of artillery to control avalanches.

Response—We have thoroughly analyzed *Factor A, The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* and conclude that snowmobile use is not a threat to the GYE population now or in the foreseeable future (see discussion above under *Factor A*). The Forest Plan Amendment includes guidance that, inside the PCA, localized area restrictions are to be used to mitigate any conflicts during denning or after bear emergence in the spring. Bears tend to den in remote areas with characteristics that are not conducive to snowmobiling (*i.e.,* steep, forested habitats). Suitable denning habitat is well distributed on the forests, and much of the general grizzly bear denning habitat identified in the Forest Plan Amendment Final EIS as being open to snowmobiling is not actually used by snowmobiles (USDA FS 2006a, p. 92). For example, 85.2 percent of the known dens in the GYE are located in areas where snowmobile use does not occur and, of the 13.9 percent of dens that do occur in areas open to snowmobiling, only 0.8 percent are classified as high potential for snowmobile use (Haroldson 2017d, *in litt.*).

Since 2002, we have consulted with all of the GYE National Forests at least once regarding the effect of snowmobiles on denning grizzly bears (Caribou-Targhee NF 2004, p. 15; Dixon 2016, *in litt.*). While the potential for disturbance exists, USFS and IGBST monitoring over the last 3 years has not documented any disturbance or conflict (Haroldson 2016, *in litt.*). Additionally, during the winter of 2009–2010, a grizzly bear was observed digging a den in the Squaw Basin, Bridger-Teton National Forest in an area heavily used by snowmobiles (Hegg *et al.* 2010, pp. 23–28). The grizzly bear remained in the den throughout the winter and emerged April 20, 2010, with one cub-of-the-year. Thus, our best available information suggests that current levels of snowmobile use are not appreciably reducing the survival or recovery of grizzly bears.

As we stated in the proposed rule (81 FR 13174, March 11, 2016), the available data about the potential for disturbance while denning and den abandonment from nearby snowmobile use are extrapolated from studies examining the impacts of other human activities and are identified as ''anecdotal'' in nature (Swenson *et al.* 1997, p. 37) with sample sizes so small they cannot be legitimately applied to assess population-level impacts (in their entirety: Harding and Nagy 1980; Reynolds *et al.* 1986; Hegg *et al.* 2010). Because there are no data or information suggesting that snowmobile use in the GYE is negatively affecting the grizzly bear population, or even individual bears, we determine that snowmobiling does not constitute a threat to the GYE grizzly bear DPS now, or in the future. Yet, because the potential for disturbance and impacts to reproductive success exists, monitoring will continue to support adaptive management decisions about snowmobile use in areas where disturbance is documented or likely to occur.

Inside YNP, the use of an avalanche management system is limited to Sylvan Pass to prevent avalanches from covering the road, and the Superintendent has the ability to consider the location of wintering wildlife and close Sylvan Pass. Furthermore, there have been no documented mortalities or disturbances of denning grizzly bears as a result of avalanche control. Avalanche control for snowmobiling does not occur on any of the National Forests within the DMA. Therefore, we conclude that avalanche control activities are not a threat now, or in the foreseeable future, to GYE population.

Issue 57—Commenters expressed concerns with threats associated with off-road vehicles (ORV) and mountain bike use on National Forest lands. Commenters stated that an increased use of ORVs on highly accessible public lands will greatly increase the risk of grizzly bear mortality. Commenters suggested that in order to adequately address this threat, managers need to develop more stringent ORV regulations prior to delisting. Commenters also stated that the Service failed to address threats associated with mountain bikes and that regulation is needed despite the fact that these risks are unknown.

Response—Limiting motorized recreation, including ORV use, is a fundamental component of the 2016 Conservation Strategy, hence the requirement for no net decrease in secure habitat inside the PCA (see Issues 43 and 49). This measure directly limits the total area affected by motorized recreation, so that grizzly bears have adequate secure habitat regardless of the number of people using motorized trails. Limitation of non-motorized recreation, including mountain bikes, is not a component of the 2016 Conservation Strategy because we've concluded that the current and projected levels of use will not substantially impact the GYE grizzly bear population. Because mountain bikers often travel quietly and at high speeds, when combined with environmental factors (*e.g.,* dense vegetation, hilly terrain, and running water), they may be more likely to be within 50 m (164 ft) before being detected by a bear (Schmor 1999, pp. 118–119). MacHutchon (2014, p. 37) concluded that an alert mountain biker making sufficient noise and traveling at slow speeds would not be more likely to have a sudden encounter with a bear than would a hiker. The 2016 Conservation Strategy's adaptive management approach will allow managers to respond to detrimental levels of non-motorized recreation, should they occur, on a case-by-case basis and also provide managers with the data necessary to determine if ecosystem-wide limitations may be necessary in the future.

Issue 58—Several commenters raised concerns about human encroachment into wildlife habitat claiming that grizzly bears are not resilient to human persecution or habitat degradation (Ripple *et al.* 2016). Specifically, they cited potential effects of increased human recreation and visitation in bear habitat including: (1) Increasing numbers of encounters, as well as long-term exposure of bears to humans, results in higher mortality risks; and (2) potential exclusion of bears from habitat since grizzly bears are twice as likely to use an area when human activity is restricted or when people are inactive (*i.e.,* nighttime) (Coleman *et al.* 2013). One commenter stated that the Service needs to better analyze current habitat security and isolation from people and predict how it will change in the foreseeable future, in all types of grizzly bear habitat.

Commenters also proposed potential management responses that could alleviate these impacts including: (1)

Enhancing infrastructure to support increasing park visitation, although conversely, a peer-reviewer suggested limiting visitation to YNP and GTNP; (2) assessing human visitation as ''take'' under section 9 of the Act because it harasses wildlife and causes displacement from food sources; (3) restricting human access to particular habitats during times of food shortages; (4) imposing food storage orders on all habitat within the DPS boundaries, especially within the DMA, to the maximum extent possible within the law; and (5) increasing I&E for tourists and hikers.

Response—We have thoroughly analyzed *Factor A, The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* and conclude that human recreation is not a threat to the population now or in the foreseeable future. Our habitat management standards rely heavily on reducing anthropogenic influences and minimizing grizzly bear-human conflicts because excessive human-caused mortality and subsequent population decline was the primary factor that led to the original listing as threatened in 1975. For a detailed explanation of this rationale, please refer to Issue 41, the *Habitat-Based Recovery Criteria* section of this final rule, and the 2016 Conservation Strategy (YES 2016a, pp. 54–85).

A survey of grizzly bear experts showed that research on the potential impacts of habituation as a result of human recreational activities should be a high priority (Fortin *et al.* 2016, p. 17). Although Herrero (1985, pp. entire) found that habituated bears were at an increased risk of being involved with conflicts, other research has found that habituated bears were less likely to be involved with conflicts (Jope 1985, p. 36; Nadeau 1987, pp. 20, 46–48; Aumiller and Matt 1994, pp. 53–58; Gunther and Biel 1999, p. 3). Although some research has found that grizzly bears avoid human activity (Coleman *et al.* 2013, pp. 1317–1317) or newly logged forests (Pigeon *et al.* 2016, pp. 1107), these avoidances were temporal with grizzly bears returning to the area at different times of the day. Fortin *et al.* (2013b, entire) found that grizzly bears are extremely flexible in their ability to switch activity profiles (*i.e.,* nocturnal versus diurnal) without being negatively impacted by these switches.

Section 7 of the Act will no longer apply to the GYE population upon finalization of this rule. However, the Service considers the establishment of habitat thresholds for human population growth and limits on levels of human recreation to be unrealistic and concludes that the 1998 baseline will adequately address these issues through access management, limitations on site development, and I&E efforts. See Issues 45, 54, and 108 for additional information. Under the 2016 Conservation Strategy, a multi-agency effort will be conducted to determine the best long-term solutions for alleviating the pressures of increased visitation and the potential need for increased infrastructure.

Issue 59—Comments from the public and peer-reviewers expressed concern about the potential future impacts of logging on grizzly bears in the GYE, including that: (1) 11 Percent of suitable habitat outside the PCA, but inside the DMA, allows timber harvesting; and (2) timber harvest would increase after delisting since there would no longer be limits on road densities in grizzly bear habitat, opening more than 3 million acres to timber harvest and road building.

Public comments provided varied perspectives on the impacts of logging on grizzly bears including: (1) Grizzly bears avoid recently logged forests (McClellan and Hovey 2001; Apps *et al.* 2004), potentially because these areas are warmer; (2) logging disturbs denning bears, particularly females; (3) timber harvest can degrade habitat quality under ''short-rotation management regimes'' (Mattson and Knight 1991); (4) food availability does not increase in early successional forests in the GYE; (5) logging could degrade red squirrel habitat (and red squirrels help make whitebark pine nuts available for grizzly bear consumption); and (6) there is not currently enough science to determine the impacts of logging on bears, besides the research on grizzly bear mortalities from roads. One commenter noted that, unless no logging occurred between 2002 and 2016, we need to analyze impacts of logging after 2002.

Commenters also suggested that future management may worsen these impacts, including that: (1) The USFS could ignore habitat protections for grizzly bears that limit logging as previously occurred in Targhee NF; and (2) timber harvest lands adjacent to YNP (and in wildlife migration routes) will be designated Farm Bill priority lands, resulting in a less rigorous review. Suggestions on how to minimize these impacts included: (1) Mitigation for projects that impact secure habitat should not include land that has already been disturbed (*e.g.,* previously logged land); and (2) grizzly bears should remain listed to avoid logging in their habitat. Conversely, a commenter suggested that timber harvest is part of responsibly managing natural resources and that bears are flexible and can adapt to multiple use landscapes.

Response—Inside the PCA, secure habitat must be maintained at or above the 1998 baseline, and application rules for changes to secure habitat will apply. These rules limit changes to secure habitat to one project at a time within a bear management subunit and the impact of that project cannot exceed 1 percent of the area of the largest subunit within that BMU (YES 2016a, pp. 62–63). For permanent changes, replacement habitat must be in place for at least 10 years before it can be used for mitigation for future projects, including logging. These rules ensure that ''short-rotation management regimes'' will not occur within the PCA. In addition, although roughly 17 percent or 3,967 km^2 (1,532 mi^2) of suitable habitat outside the PCA is identified as having both suitable timber and a management prescription that allows timber harvest, from 2003 to 2014, an average of only 4.7 km^2 (1.8 mi^2) was actually logged annually (Jackson 2017, *in litt.*). The IGBST would be able to detect any changes to the population as a result of changes in habitat through their demographic monitoring of the GYE grizzly bear population, which they will report to the YGCC who could then decide if modifications to the 2016 Conservation Strategy are necessary to maintain a recovered grizzly bear population in the GYE.

Timber is the primary resource extracted in grizzly bear habitat. Habitat quality (as a function of road density and timber harvest) has improved as a result of declining timber harvest, decreasing road construction, and increasing road decommissioning since the mid-1990s (USDA FS 2006a, pp. 156, 200). Timber harvest volumes and road construction have declined since the mid-1990s. Under the 1998 level of secure habitat, the GYE grizzly bear population has tripled in size and has stabilized from 2002–2014 as it has reached carrying capacity (Haroldson *et al.* 2014, p. 13; van Manen 2016a, *in litt.*). From 1986 to 2002 there has been a net reduction of more than 1,600 km (1,000 mi) of road on the six GYE National Forests (inside and outside the PCA). Inside the PCA on National Forests, there was an average reduction (elimination) of 59.9 km (37.2 mi) of road per year from 1986 to 2002 (USDA FS 2006a, p. 200). Similarly, outside the PCA, there was an average reduction of 40.7 km (25.3 mi) of road per year for this time period (USDA FS 2006a, p. 200). Timber lands immediately adjacent to the YNP are contained within the PCA and protected under the 1998 baseline standards for secure

habitat and developed sites. The standards and guidelines adopted in each Forest Plan, and the Planning Rule under which they fall, must still be abided by when considering a project under the 2014 Farm Bill.

Please see the *Vegetation Management* section of this final rule for discussion of how timber harvest may impact grizzly bears, Issue 61 for further discussion of bear use of newly disturbed forests, and the *Snowmobiling* section of this final rule and Issue 45 for discussion of potential den site disturbance. Apps *et al.* (2004, p. 148) cautioned that their findings that grizzly bears avoided newly logged areas may be a result of an ''accelerated rate of conifer regeneration of cutblocks,'' ''lower shrub cover than would otherwise be expected,'' and they were ''associated with higher human access and influence.'' Although Pigeon *et al.* (2016, p. 1107) found that grizzly bears avoid newly logged forests, this was a temporal avoidance of the warmest parts of the day and grizzly bears returned to the area at cooler times of the day. Fortin *et al.* (2013b, entire) found that grizzly bears are extremely flexible in their ability to switch activity profiles (*i.e.,* nocturnal versus diurnal) without being negatively impacted by these switches.

Issue 60—Commenters expressed concerns with our discussion of the impacts to grizzly bears from human population growth and development activities on private lands in the GYE, including that: (1) Increasing development of formerly rural areas has negative impacts on grizzly bear population trends (Doak and Cutler 2014); (2) the 1998 baseline does not consider the impacts of edge effects with residential and recreational developments on private lands; (3) we need more discussion of how to minimize grizzly bear deaths and conflicts on private lands; (4) the potential privatization of Federal land could pose a threat to habitat maintenance (especially when it is easier to transfer Federal land to private control if it does not contain listed species); (5) the States (especially Montana and Idaho) have no substantive management restrictions in grizzly bear habitat on private lands; and (6) the Service does not have a system to monitor the impacts of population growth and increased development.

Concerns from commenters on management strategies for bear conservation on private lands included: (1) Questions as to how ''take'' prohibitions will apply to degradation of bear habitat on private lands since ''take'' includes habitat destruction, in addition to killing and harassing endangered animals; (2) suggestions to apply a ''no net loss'' policy for grizzly bear habitat on private lands; (3) suggestions that the Federal Government should use public lands to mitigate for impacts to grizzly bears that occur on private lands; and (4) suggestions that we need to consider how implementation of the 2016 Conservation Strategy will impact private landowners in the DMA, potentially adversely, since the process for meeting damage claims on real and personal property could be mired in delays. A peer-reviewer emphasized that education and mitigation will be key strategies in reducing the likelihood of ''attractant sinks'' (*i.e.,* increased human-caused grizzly bear mortalities as a result of unsecured attractants) developing on the 9 percent of suitable habitat outside the PCA that is private land.

Response—Private lands comprise 2.1 percent of the PCA and 9 percent of suitable habitat outside the PCA. The consideration of private land activities on grizzly bear-human conflicts is fundamental to the proper management of grizzly bears and to human safety because these conflicts often lead to grizzly bear mortality. However, the vast majority of suitable grizzly bear habitat is secure on public land (*i.e.,* National Parks or National Forests). Thus, despite the conflicts that arise on private lands, we conclude that activities on private lands do not constitute a threat to the GYE grizzly bear now or in the future.

In regard to potential privatization of Federal public land posing a threat to grizzly bears in the GYE, while changes to the protected status of grizzly bear habitat on these public lands is theoretically possible, such an outcome is highly improbable, especially at the scale that would be necessary to affect the viability of the GYE grizzly bear population. Although Doak and Cutler (2014a, p. 313) graph the increase in rural population trends from 1975 to 2005, they do not include rural population trends in their modeling of population trends in the GYE (see Issues 28 and 29 for discussion on a rebuttal to Doak and Cutler 2014a).

Suitable habitat excludes areas of increased mortality risk (*e.g.,* high population densities and sheep allotments; ''edge'' habitat). However, these population sinks are included in the DMA, the area in which the mortality limits apply, as set forth in this final rule, the 2016 Conservation Strategy, and the revised Demographic Recovery Criteria. These mortality limits apply to all lands within the DMA, private and public. The amount of suitable habitat, including the 1998 baseline levels of secure habitat and developed sites, are sufficient to maintain a viable grizzly bear population in the GYE. However, the habitat standards set forth in this rule and the 2016 Conservation Strategy apply only to Federal lands and, therefore, will have no direct effect on private landowners. Upon delisting, current programs that compensate owners for livestock losses will continue in Idaho, Montana, and Wyoming regardless of the listing status of the grizzly bear (see Issue 54).

Limits on developing private lands to reduce conflicts with resident wildlife are the responsibility of the counties and the States, both of which have representatives on the YGCC; the Service has no direct authority over private lands. As previously stated, section 9 take prohibitions of the Act will no longer apply after this final rule goes into effect. Because a disproportionate number of grizzly bear-human conflicts occur at site developments on private lands (see Servheen *et al.* 2004, p. 15), we recommend that private landowners become involved in efforts to reduce these conflicts. We, in conjunction with the counties and State wildlife agencies, will continue to promote outreach, education, and management of land development activities in grizzly bear habitat to reduce bear-human conflicts upon delisting. State bear management specialists will continue to respond to human-bear conflicts and efforts to reduce conflicts on both public and private lands (YES 2016a, pp. 86–95). These efforts to limit conflicts on private lands will continue under the YGCC's management, which will be informed by future IGBST demographic reviews.

Issue 61—One commenter asked about the role of fire in grizzly bear habitat and how fire, both natural and human-induced, might be managed post-delisting.

Response—Blanchard and Knight (1990, p. 592) found that the 1988 fire resulted in the probable deaths of only a few grizzly bears and no increase in bear home range sizes or daily movement rates during or after the fire. Immediately after the fires had passed, grizzly bears moved into the burned areas to feed on the increased availability of burnt ungulate carcasses, roots, ants, and newly emerged grasses and forbs. Although some grizzly bears avoided burned sites in the year after the fire (1989), use of burned areas in subsequent years (1990 to 1992) suggested that fires increased production of forbs and roots and were,

therefore, beneficial to grizzly bears (Blanchard and Knight 1996, pp. 120–121). The period of most robust grizzly bear growth (4 to 7 percent) occurred shortly after the 1988 fires, through the entire decade of the 1990s. The USFS uses multiple fire management strategies to minimize potential negative threats (*i.e.,* to life and structures) while allowing fire to maintain its natural role in an ecosystem. Management strategies include the use of prescribed fires to ''maintain or improve habitat conditions'' for wildlife (Caribou-Targhee NF 2005, p. 11; USDA FS 2011, pp. 3–4; Shoshone NF 2012, p. 2; Bridger-Teton NF 2015, pp. 8, 10). Please see the *Factor E: Catastrophic Events,* above, for further discussion on the potential impacts of fires and management practices.

Issue 62—Several public commenters and a peer-reviewer raised concerns over habitat fragmentation. Specifically, commenters noted that: (1) There is already a high degree of fragmentation of suitable habitat within the PCA and, to a greater degree, within the DMA (Merrill *et al.* 1999; Carroll *et al.* 2001; Merrill and Mattson 2003; Johnson *et al.* 2004; USDA FS 2006a; Schwartz *et al.* 2010); (2) we did not acknowledge the negative effects of this fragmentation in our proposed rule, such as genetic ''isolation'' of grizzly bears, ''reduction of species richness, inbreeding, and loss of sustainability of the habitat'' (Fahrig 2003) or on the quality and conservation of available habitat; (3) private land uses, energy development, timber harvest, ORV use, and livestock allotments are potential sources of further habitat fragmentation, especially outside the PCA; and (4) there was no provision in the rule designed to limit habitat fragmentation within the DPS boundary outside of the DMA. Lastly, one commenter suggested that the States be required to manage for decreasing fragmentation.

Response—All the best available biological information demonstrates that suitable habitat, including fragmented and unfragmented areas, contains the habitat necessary for a healthy and viable grizzly bear population in the long term. Please see Issues 40 and 96 for discussion on suitable habitat and the impacts of genetic isolation on the GYE grizzly bear population, respectively.

Issue 63—A few public comments assumed that most or all of the GYE is designated as critical habitat for the grizzly bear.

Response—In 1976, we proposed to designate critical habitat for the grizzly bear (41 FR 48757, November 5, 1976). This designation was made stale by the 1978 critical habitat amendments to the Act, including the requirement to perform an economic analysis. This proposal was never finalized. Recognizing the importance of habitat to the species, instead, the IGBC issued habitat management guidelines within all occupied grizzly bear habitat (USDA FS 1986, entire). These habitat management guidelines are considered to be one of the primary factors in successful GYE grizzly recovery efforts.

Human-Caused Mortality Issues (Factors B and C Combined)

Issue 64—Public commenters expressed opinions both for and against the hunting of grizzly bears in the GYE. Substantive comments in favor of hunting indicated that it is an appropriate management tool to: (1) Help maintain a balance between an adequate grizzly bear population and adequate food resources; (2) address conflict bears and minimize future conflict with humans; (3) create opportunities for bears from other populations to immigrate into the GYE, thereby improving genetic diversity for the GYE grizzly bear; and (4) be a source of funding for grizzly bear monitoring and conservation.

Conversely, substantive comments in opposition to hunting covered a range of issues, including that: (1) There is a lack of scientific data to support hunting and discount it as a substantial threat because it will be adding to the current levels of human-caused mortality that will not decline after delisting; (2) we did not adequately consider how hunting could impact the grizzly bear population given the species' slow reproductive cycles; (3) we should institute a 5- to 10-year moratorium on hunting after delisting to allow the grizzly bear population to reach at least 850 to 1,000 bears and there is a self-sustaining population outside the DMA, to see how State management impacts populations, and to allow for additional research on the potential impacts of a hunt; (4) hunting could cause an increase in immigration of new males that result in female avoidance via the use of less suitable habitat and thus smaller litter sizes, as well as those males committing infanticide, further depressing population numbers; (5) hunting could negatively impact grizzly bear behavior including orphaning of young and the disruption of activity patterns during denning; (6) hunting is an ineffective management tool, noting that it could lead to inbreeding and eventual extinction, hunters are likely to target the largest, fittest animals, rather than conflict bears, and that there is no evidence that hunting bears will increase grizzly bears' fear of humans; (7) States will have incentive to allow regular exceedance of grizzly bear mortality limits in order to maximize numbers of moose and elk for ungulate hunters; and (8) hunting could erode support for wildlife recovery.

Response—We agree that hunting can be an appropriate management tool to address conflict bears and minimize future conflict with humans by replacing management removals, if removals are properly targeted, and raising funding for conservation through hunting tag sales. However, while hunting may indirectly reduce competition for food among intra-specifics by reducing the number of individuals in the GYE, wildlife populations regulate themselves naturally (Caughley and Sinclair 1994, pp. 100–119), and we, therefore, do not believe hunting is necessary to ''balance an adequate grizzly bear population and adequate food resources.'' Additionally, although hunting may increase the number of mortalities in the GYE, we believe many of these mortalities would replace management removals. Further, the number of mortalities is ultimately limited by demographic recovery criterion #3 (as outlined in the 2016 Conservation Strategy). Therefore, we do not believe that hunting would create many more opportunities for immigration than currently exist. States have demonstrated their expertise in managing wildlife, particularly game species as indicated by the relative health of most game species in the U.S. We are confident that if the States institute a hunt, that it will be carefully regulated with yearly ecosystem-wide coordination to insure that total mortality remains within the sustainable limits for each age/sex class as set forth in this final rule, the 2016 Conservation Strategy, and the Revised Demographic Recovery Criteria.

We appreciate that many commenters have concerns regarding hunting of grizzly bears. Hunting is a discretionary mortality source that will occur only if mortality limits from all other causes have not been exceeded (YES 2016a, pp. 33–50). Because the sustainable mortality limits for independent males and females include mortalities from all sources (YES 2016a, p. 36), including hunting, and are applied within the DMA, hunting should never threaten the GYE grizzly bear population. Hunting permits will not be issued by the States if mortality limits are exceeded.

Hunting is regulated by the States who will again have management authority and jurisdiction to regulate any future hunting when this final rule goes into effect as discussed in *Factors*

B and C Combined, above. Through their regulations and the Tri-State MOA, the States have made assurances that grizzly bear management, including hunting, will be managed cooperatively between the three States to ensure that a recovered grizzly bear population is maintained. As discussed above, the GYE population at its current level no longer meets the definition of a threatened or endangered species; therefore, it is not necessary to further increase the population inside or outside of the DMA.

The limited hunting that may occur in the GYE if States choose to institute a hunt will be carefully controlled and would be unlikely to affect population dynamics. Some evidence of infanticide has been found in North American and European brown bear populations (McLellan 1994, pp. 15–16; Swenson *et al.* 1997, p. 450), which can reduce the population growth rate through cub mortality; however, Miller *et al.* (2003, p. 144) and McLellan (2005, pp. 153–154) could not find evidence of population-level effects of sexually selected infanticide in North American grizzly bear populations. If hunting preferentially removed adult male bears, and if infanticide was common, hunting might result in some reduction in cub survival in localized areas. However, this would likely have little impact on overall population growth rate because hunting mortality on males would be limited in numbers and extent. We do not anticipate that the male-to-female ratio would change markedly under the adopted mortality limits or that sexually selected infanticide would become an issue affecting population trajectory of the GYE grizzly bear population. Continued monitoring of the population through radio telemetry and observations of unmarked reproductive females will alert the IGBST to any substantial changes in cub survival or production and trigger appropriate management responses.

Although disturbances caused by hunting during denning may have negative effects on individual survival and reproduction (Swenson *et al.* 1997, p. 37, Linnell *et al.* 2000, pp. 401, 408), there is no evidence of resulting population-level impacts (in their entirety: Harding and Nagy 1980; Reynolds *et al.* 1986; Hegg *et al.* 2010). In addition, there is no data or information suggesting that human recreational activity is negatively affecting the GYE grizzly bear population. The IGBST will produce an annual population estimate for the DMA that will be used by the States to establish total mortality limits for each age/sex class for the following year. Hunting seasons will be managed by the States so as not to exceed those mortality limits. Hunting seasons will be closed within 24 hours of meeting total mortality limits, and any mortality exceeding those limits will be subtracted from that age/sex class total mortality limit for the following year per State rules and regulations (see discussion above under *Factors B and C Combined*). A management review also will be conducted by the IGBST every 5 to 10 years to assess if recovery criteria are being maintained. Consequently, any potential changes to grizzly bear behavior caused by hunting that impact population numbers or distribution criteria would be accounted for in subsequent hunting seasons.

In regard to hunting being an ineffective management tool, research by Swenson (1999, pp. 159–160) showed that brown bears were more wary of humans in areas where brown bear hunting occurred. To our knowledge, there is no data or information that hunting would decrease the overall fitness of individuals in the GYE grizzly bear population. Hunting can be used as a compensatory mortality source, targeting bears that would otherwise be removed by management action. However, as explained above, States will authorize hunting only as long as the overall mortality limits are not exceeded. The IGBST and State agencies collect data on grizzly bear-human conflicts and will continue to do so after delisting. These data are reported and displayed spatially in the IGBST's Annual Report. Any changes in the frequency, location, or nature of grizzly bear-human conflicts would be detected. State regulations (see *Factors B and C Combined*) will prevent regular exceedance of grizzly bear mortality limits. Exceedance of the total mortality limits for 3 consecutive years would trigger an IGBST Biology and Monitoring Review, and the Service can also initiate a status review independent of the IGBST or the YGCC should the total mortality limits be exceeded by a significant margin or routinely violated or if substantial management changes occur significant enough to raise concerns about population-level impacts.

Issue 65—We received many comments from both the public and peer-reviewers regarding hunting boundaries. Peer-reviewers and other commenters sought clarification regarding whether or not hunting would be allowed within the PCA, since it is defined as a ''secure area.'' Several comments recommended that no hunting should be allowed within the PCA, the DMA, secure habitat, JDR, GTNP (including on State or private inholdings), in Montana's Taylor Fork drainage, at food aggregate sites, or in other densely populated grizzly bear areas, while others suggested that all Federal lands should be open to hunting or that hunting be focused in areas prone to human-grizzly bear conflict. Peer-reviewers and public commenters suggested that hunting be prohibited in connectivity areas and key wildlife corridors. Many commenters suggested that Wyoming must recognize NPS' jurisdiction over the JDR or Wyoming would be violating the National Park Service's Organic Act. Noting that the boundaries of the PCA and ''secure habitat'' are hard to identify, comments suggested that hunting be limited to zones that are easier to define geographically. Some commenters suggested that State managers create a buffer around YNP and GTNP in which no hunting would be allowed since bears in those areas are more used to humans and thus more vulnerable to hunters. Additionally, comments requested that we assess the impacts of grizzly bear hunting on park inholdings.

Response—As we explained in Issue 64, after de-listing, any future hunting would be regulated by the States. In most cases the public has opportunities for input when the State is adjusting hunting and management regulation. All hunting of grizzly bears will remain prohibited within National Park lands, which comprise 39.4 percent of the PCA. Hunting will be allowed on private lands and other public lands within the PCA. Within the JDR, the Secretary of the Interior is required to permit hunting in accordance with applicable Federal and State law, with exceptions for public safety, administration, or public use and enjoyment (Pub. L. 92–404, Sec. 3.(b)). However, the State of Wyoming has indicated they do not intend to allow hunting in the JDR (Mead 2016, *in litt.*).

See Issue 40 for the definition of secure habitat; the risk of human-grizzly bear conflicts is reduced in secure habitat as a result of habitat management. However, hunting may occur in secure habitat where authorized by applicable Federal and State laws and will be limited by the applicable annual mortality thresholds (see table 1). Hunt areas and hunt area boundaries outside NPS and Tribal lands will be addressed in State hunting regulations, which are under the purview of the State Fish and Game Commissions. See *Factors B and C Combined* and Issue 77 for more details about how the States set harvest regulations.

The total annual mortality limits inside the DMA by definition include any grizzly bear legally harvested on NPS inholdings. Any grizzly bears occupying private land inholdings within NPS boundaries are inside the DMA and are a part of both the annual population estimate and annual mortality limits, and as such, were explicitly considered during the analysis conducted in the preparation of this final rule.

The management of conflict bears within the GYE grizzly bear DPS boundaries will be based upon existing laws and authorities of State wildlife agencies and Federal land management agencies, and directed by protocols established in the 2016 Conservation Strategy and State management plans. Wyoming has indicated that they intend to ''emphasize harvest in high conflict areas which typically occur a significant distance from National Park boundaries'' (Mead 2016, *in litt.*). Inside YNP and GTNP, grizzly bear biologists will continue to respond to grizzly bear-human conflicts. In all areas outside of the NPs, State and Tribal wildlife agencies will continue responding to grizzly bear-human conflicts. All three State fish and wildlife agencies have significant expertise in using hunting as a management tool to reduce conflicts with a number of species.

Issue 66—We received comments from peer-reviewers and the public expressing concerns with proposed mortality limits (total, independent females, and independent males). A number of commenters questioned the biological justification for: (1) Allowing any discretionary mortality at populations less than 674 bears; (2) lowered mortality rates for independent females and dependent young, but unchanged and relatively high mortality rates for independent males; and (3) independent female mortality limits greater than 7.6 percent (at any population size). Additionally, commenters asked what the mortality rate would be at population levels less than 600 to ensure population growth; these commenters suggested that merely halting all discretionary mortality would not be a sufficient response. A few commenters noted that other larger, more connected populations have much more conservative total mortality limits than the ones in our proposed rule. In order to increase confidence in the biological basis of mortality limits, commenters suggested independent peer-review of the models used to derive mortality thresholds.

A number of commenters requested additional clarification in our mortality limits, such as: (1) An explanation on uncertainty around estimated mortality limits; (2) ''what point within the 95 percent confidence interval the population size estimate refers'' when discussing mortality rates; (3) what the mortality rate would be at population levels less than 674 bears (*i.e.,* how much less than 7.6 percent); (4) whether mortality limits undergo annual peer-review, would be recalculated annually, and how variability would impact management; and (5) how the proposed 7.6 percent mortality rate for independent females will maintain stability when a 9.0 percent mortality rate was required for stability in the 2007 Recovery Plan supplement. Peer-reviewers also requested example calculations of the number of allowable discretionary mortalities from hunting and management removal for each sex and age class for various population sizes (*e.g.,* show how many bears would have been available for hunting from 2002 to 2014 and how many years would have allowed no hunting).

Commenters worried that the proposed mortality limits could be easily exceeded (especially with hunting) and could lead to population declines because: (1) Undetected population declines could result from male bears being killed nearly twice as often as female bears; (2) models run by commenters show high probabilities of population decline below 500 bears with our proposed mortality limit framework, declines that could go undetected because of our insensitive population estimates based on females with cubs-of-the-year; (3) it will be difficult to close the hunting season when total mortality limits are reached because as many as half of grizzly bear mortalities occur in non-telemetered bears and are unknown (McLellan *et al.* 1999); (4) population thresholds at which mortality rates change (*e.g.,* 600 and 674) are only estimates (resulting from an estimation method with which the commenters took issue, see Issue 28); and (5) population estimates will be based on populations within the entire ecosystem (including National Parks), but will establish discretionary mortality in areas outside of the National Parks. Several commenters requested that we provide a full analysis of how proposed mortality thresholds will impact population numbers, dispersal, and connectivity, with one individual recommending an Environmental Impact Statement (EIS) to evaluate alternative mortality limits and habitat protections. Lastly, commenters worried that revisions to the population sex-age structure, and associated mortality limits, will happen too infrequently because it is a discretionary option for States only if mortality thresholds are violated for 3 years in a row.

We received several comments from the public suggesting adjustments to our proposed mortality limits including: (1) Mortality limits should be more conservative to account for bias associated with the population size and trend and potential threats from an expanding urban-wildland interface; (2) mortality limits should be set at the lower end of the confidence interval because the use of average estimates for vital rates, mortality rates, and population size means there is a 50 percent chance that mortality limits are too high and unsustainable; (3) cumulative annual mortality should be indexed monthly or seasonally to alert managers if mortality limits may be exceeded, with a trigger to stop discretionary mortality for the year; (4) discretionary mortality should cease when the population estimate is less than 674 rather than less than 600 bears; (5) if discretionary mortality is allowed at less than 674 bears, then total human-caused mortality should be at the threshold proposed in the 2007 Recovery Plan: Supplement to the Demographic Recovery Criteria; (6) hunting should halt when the lower bound of the 95 percent confidence interval of the population estimate is less than 600 bears; and (7) only a fraction of the estimated population available for discretionary mortality should be harvested to avoid overharvest due to uncertainty in population size, a strategy known as proportional threshold harvesting. Peer-reviewers also proposed how to adjust mortality limits in the future, including: (1) Discretionary mortality should change in response to potential changes in sex-age classes; and (2) hunting limits should consider annual changes in environmental conditions (*i.e.,* drought, fire, or berry crop failures). In addition, a commenter suggested that hunting targets should be spatially explicit, concentrating mortality in the southern and eastern portions of the GYE while encouraging expansion to the west and north.

Response—The biological basis for the 7.6 percent mortality threshold for independent females was based on models presented in IGBST (2012, entire) and would maintain an average population size around 674 (which is the estimate for the time period 2002 to 2014, the timeframe during which the population began to demonstrate density-dependent population regulation). This mortality threshold was reduced from 9 percent in 2007 to

the 7.6 percent current threshold because of changes in vital rates (IGBST 2012). The premise behind the 9 percent and 10 percent sustainable mortality rates when the population is greater than 674 is that a higher mortality rate would likely allow the population to return back to the long-term average of 674, consistent with the recovery criteria and the States' management commitments.

Whereas the IGBST is currently investigating the power of the Chao2 technique to assess how soon we can detect a change in population trend may be reached under the 9 percent and 10 percent scenarios, and how far the population may already be below the objective of 674 when this is detected, the premise for this adaptive management approach is well established in the literature. There is uncertainty around the mortality estimates due to unknown/unreported mortalities, but YES managers expressed a desire to rely on the central tendency of the data rather than reporting credible intervals as it would substantially complicate implementation of mortality monitoring (see Issue 33). Given that the Chao2 estimator underestimates population size, particularly at higher densities (Schwartz *et al.* 2008, figure 5), the concern that mortality limits should be more conservative to account for bias associated with the population size and trend is unfounded. Currently, there is no evidence that the age of first reproduction is increasing.

On the issue of the 50 percent chance that mortality limits are unsustainable, this is correct if mortality limits are reached every year. Decisions whether to set the mortality limits at the lower end of the confidence interval on the population estimate or based on the point estimate itself are mostly policy issues; from a scientific standpoint, however, there is justification for basing management decisions on the central tendency of the data, *i.e.,* the point estimate of population size (see Issues 28 and 33). It is important to point out that the 7.6 percent used in the GYE is a threshold for total mortality, and is thus not directly comparable to mortality rates for other populations that use thresholds for human-caused mortality. Taking this into account, the sustainable mortality thresholds used for other populations are not distinctly different from those applied in other populations. Furthermore, if any population estimate falls below 600, there will be no discretionary mortality, except as necessary for human safety.

In response to comments about the potential to overshoot the population objective, see Issue 19. There is indeed a lag time and, thus, the potential for the population to drop below the long-term average of 674. The States have indicated that they will manage the population around the long-term average, and we recognize that the population abundance will vary above and below that point estimate. IGBST is currently investigating the power to detect when a population objective has been reached and by the time it is detected, the degree to which the population objective may be exceeded in terms of time and population size. The determination of when mortality thresholds are reached is based on total mortality, which includes a statistical estimate of the number of unknown/unreported mortalities. The IGBST uses a similar method as McLellan *et al.* (1999, pp. 913–914) to estimate unknown/unreported mortalities, but our estimates of unknown/unreported mortalities are actually higher (as discussed in the preceding paragraph); for every reported mortality, our estimates are closer to two unreported mortalities. The estimate of unknown/unreported mortalities allows a full accounting of total mortality and thus ensures that hunting mortality does not contribute to exceeding allowable mortality thresholds.

In response to the suggestion of a monthly or seasonal mortality index, the IGBST already summarize mortalities on a continuous basis (*i.e.,* as records come in) and would allow for managers to be alerted in a timely manner if mortalities were exceeded. This information is posted on the IGBST Web site (under mortality tables; see Issue 26) and is available to both the public and managers. In addition, the IGBST is able to calculate unknown/unreported mortality every time a mortality is added to the mortality database so that the hunting season can be closed by the States if allowable total mortality is exceeded. Idaho and Wyoming regulations state that all hunting shall be suspended in the DMA if total mortality limits for any sex/age class identified in the management plan are met at any time (Idaho Fish and Game Commission 2016, p. 2; Wyoming Game and Fish Commission 2016, p. 67–2). Montana regulations state that if a State meets any of its allocated regulation harvest limits at any time of the year, the respective State will cease hunting in the DMA (Montana Fish and Wildlife Commission Resolution, July 13, 2016 approving the Tri-State MOA). Calculation of these allocated regulated harvest limits take into consideration total, which includes unknown/unreported. The population thresholds at which mortality rates change are indeed only estimates. Management of wildlife populations is almost always based on estimates of population size; rarely are they based on a true census of population size. With a highly conservative population estimation technique due to documented underestimation bias of the model-averaged Chao2 method (see Issue 28), management decisions will also be conservative.

In response to concerns that the population estimate will not detect a decline because males will be killed at nearly twice the rate as female bears and that population estimates will be based on the entire ecosystem while hunting occurs only outside of National Parks, the IGBST uses multiple techniques for monitoring, including Chao2. Although the model-averaged Chao2 technique would not detect changes in the male subpopulation, the rates and ratios we use to derive a total population estimate are based on our known-fate analyses. The sample of radio-monitored bears (females and males) will allow the IGBST to update these rates and ratios if they change, which would be reflected in the total population estimate. If male survival declines, this would lead to lower estimates of a total population size through changes in the sex ratio, which would eventually change mortality thresholds as specified in this final rule and the 2016 Conservation Strategy. Whereas hunting mortality would occur only outside the parks, mortality management is based on the notion that grizzly bears in the GYE population form a single population, within which densities vary naturally due to differences in habitat quality, habitat security, etc. Thus, some areas currently already experience different levels of mortality. If hunting is added as a mortality source, it may change these spatial patterns, potentially changing source-sink dynamics, but total mortality would be managed so that it remains sustainable for the population as a whole. This system provides management flexibility, as it provides agencies with a mechanism to address, for example, conflict issues in certain areas while allowing potential connectivity in other areas.

Several of the more detailed assessments proposed by commenters, including the idea of an EIS, are difficult to achieve given current data. Assessing the impacts of different mortality thresholds on dispersal, for example, would be a substantial challenge and require new, concerted research efforts. Whereas such analyses would provide interesting ecological

insights, they are not essential for informing management decisions, particularly given the extensive and long-term research and population assessments conducted by the IGBST. Estimates of sustainable mortality thresholds will be updated frequently by the IGBST, and plans are under way to set up a system where they update vital rates and associated population projections annually.

From 2002 to 2014, hunting would have been allowed for independent males in 10 out of 13 years and for independent females in 7 out of 13 years. The average annual allowable allocation for discretionary mortality would have been 19 independent males and 4 independent females. Edits were made to all three documents for consistency in the mortality limits and to clarify that they apply annually. All three documents were updated to reflect that at an estimated population size of less than or equal to 674 bears the mortality limit for independent females and dependent young is less than 7.6 percent and not less than or equal to 7.6 percent.

Annually, mortality limits will be applied as set forth in table 2 of this final rule based on the previous year's population estimate. Mortality limits will be adjusted in the future based on reviews of vital rates by the IGBST every 5 to 10 years, or at any point a Biology and Monitoring Review is required. The current State regulations to maintain the mortality limits within those in table 2 will compensate for annual fluctuations in natural or other causes of mortality. These regulations include: Suspending grizzly bear hunting within the DMA if total mortality limits for any sex/age class are met at any time during the year; in a given year, discretionary mortality will be allowed only if non-discretionary mortality does not meet or exceed allowable total mortality limits for that year; and any mortality that exceeds allowable total mortality limits in any year will be subtracted from that age/sex class allowable total mortality limits for the following year.

While we respect concerns from commenters about the spatial distribution of discretionary mortality, it is outside of the scope of our decision-making authority. Hunt areas will be developed by the States in order to direct harvest where appropriate, if hunting occurs (YES 2016a, p. 20; WGFD 2016, p. 16); see Issues 64 and 65 for further discussion. There are a number of ways in which population mortality thresholds can be set and measured. The IGBST has spent considerable effort to develop the current system, with a number of workshops over the past decade and associated scientific documents (*i.e.,* workshop reports and journal articles). The monitoring system that was developed from these efforts represents the best available science. Regarding the ''proportional harvesting'' suggestion, the number of bears available for discretionary mortality, including for harvest, will be conservative because the Chao2 estimates are very conservative.

In response to suggestions to change the mortality limits and management framework, we recognize that it is unrealistic to expect to manage down to a single individual. The States agreed to manage the GYE grizzly bear population within the DMA, to *at least* within the 95% confidence intervals associated with the 2002 to 2014 long-term average grizzly bear population estimate calculated using the model-averaged Chao2 estimator (*i.e.,* 600 to 747). The Service and the States understand that the actual population will vary around that level, and that mortality will be managed to ensure that the population does not drop and remain below 600.

Issue 67—Several peer-reviewers and commenters raised concerns about the implications of limiting monitoring to the DMA. Commenters were concerned that bears outside the DMA will have no protections and a failure to count bears outside the DMA will put dispersal and connectivity in jeopardy, permanently isolating the GYE population. The States requested we remove the clause ''grizzly bears will not be persecuted because they are present there,'' in reference to the DMA, from our revised recovery criteria. One peer-reviewer commented that mortality rates may be underestimated when bears whose home ranges overlap the DMA boundary are killed outside the DMA. Commenters asserted that bears that die outside the DMA likely emigrated from the DMA and consequently should count as losses for the DMA; otherwise, threats to the population will not be accurately assessed. Peer-reviewers point out that catastrophic events within the DMA (*e.g.,* like fire in 1988), ''could displace grizzly bears forcing some to shift home-ranges to outside the DMA boundaries,'' which would require sampling outside of the DMA. One peer-reviewer noted that less monitoring outside the DMA may produce ''less data about individual bears that may behave differently than those within the DMA.'' Commenters thus requested we monitor grizzly bear populations outside the DMA or in the entire GYE DPS.

Response—The IGBST will continue to collect data on all mortalities in the GYE DPS, including those outside the DMA. However, mortalities outside the DMA will not be counted towards mortality thresholds because the DMA is the area within which IGBST partner agencies conduct population monitoring. Expanding the population monitoring beyond the DMA boundaries is not biologically justified where habitat is not suitable for the bear's long-term viability. Bears that die outside the DMA may have dispersed from within or simply have home ranges on the periphery; regardless, the population monitoring protocols that are in place would detect if the level of mortality outside the DMA reaches a point where population size inside the DMA declines. Grizzly bears throughout the GYE DPS will be classified and regulated as a game animal in accordance with State game regulations (see Issue 73).

Issue 68—We received many comments from both the public and peer-reviewers regarding the management of human-bear conflict. One commenter did not understand how our calculations of mortality rates and bear-human conflict rates are lower currently than historically (*e.g.,* during 1989 to 1998 or 1989 to 2005). This commenter suggested we should conduct such a comparative analysis at multiple population and geographic scales. Many commenters claimed that instances of human-bear conflict have increased in recent years because of overpopulation of grizzly bears, habituation, bear colonization of lower elevations and peripheral ranges due to changing food availability and distribution, increasingly close proximity to humans and developed facilities (Steyaert *et al.* 2016), and higher numbers of elk hunters. One commenter suggested that this trend could continue since Minin *et al.* (2016) found that, as land use changes, areas that will be key to carnivore conservation are also areas with high potential for conflict. One peer-reviewer commented that the current stable population trend of grizzly bears in the GYE may not confirm that the efforts to reduce human-caused mortalities are effective. One commenter suggested that managers in the GYE have not adequately carried out recommendations from the 2009 Yellowstone Mortality and Conflict Reduction Report (IGBST 2009), and that this report recommended creating a publicly available database of all bear encounters and mortalities, which still does not exist.

A few commenters weighed in on whether they thought the act of delisting would increase or decrease conflict.

Many commenters posited that delisting the GYE population of grizzly bears would reduce human-bear conflict because it will allow for more effective population management; these commenters suggested that, if bears remain on the list, and populations thus continue to grow, more bears will be removed as a result of conflicts with humans than the number of bears that would be killed in the context of a regulated hunt. On the other hand, some commenters suggested that the GYE grizzly bear population will self-regulate without delisting because disease and starvation will effectively reduce and limit the number of bears. Another commenter was worried that lethal responses to conflict would increase following delisting.

Many commenters believed we presented an inadequate discussion of methods to manage and reduce conflict; they suggested the following improvements or additions prior to delisting: (1) Improved education programs that aim to change attitudes and behaviors of people living in grizzly bear country in order to increase risk tolerance and improve willingness to share habitat (see Issue 108); (2) limits on, or elimination of, ungulate hunting to reduce defense of life and property kills; (3) incentives for hunters to retreat from downed game; (4) additional law enforcement and field staff; (5) encouragement and funding of alternatives to lethal control of bears (including additional discussion of such methods in State management plans) since lethal control does not increase public tolerance or promote avoidance of future conflict; (6) preparation of a Grizzly Bear Management Relocation Plan with pre-arranged relocation sites; (7) discussion on how managers should resolve conflicts on Tribal lands; and (8) managing for higher wild ungulate populations to decrease livestock depredation. A peer-reviewer suggested funding for programs that reduce bear attractants on public and private lands.

Commenters also provided suggestions on how to revise State management plans or the 2016 Conservation Strategy to better address conflict management, such as: (1) Explaining the 33 recommendations to abate grizzly bear conflicts in a 2006 IGBST report and incorporating these into Wyoming's grizzly bear management plan; (2) including in the 2016 Conservation Strategy the admonition that managers and citizens should not ''reward'' or ''encourage'' bears around roads, campgrounds, cities, or landfills; and (3) changes to the nuisance bear standards.

Peer-reviewers also presented a number of additional analyses that could bolster our discussion of human-bear conflict, including: (1) A review of ''the social aspects of managing large predators;'' (2) using NDVI data (satellite imagery) to understand bear distribution and how these distributions relate to human-bear conflict; (3) tracking of relocated animals to assess the efficacy of relocating problem bears; and (4) additional analysis on how to change mortality management techniques as the number of people living in and recreating in the GYE increases. Peer-reviewers also requested an explanation of how conflict bears will be treated inside versus outside the PCA.

Response—Although the total number of conflicts has increased, the rate of conflicts (number of conflicts as a proportion of the population size) has decreased since the implementation of the IGBC Guidelines (USDA FS 1986, entire). As grizzly bear abundance and distribution have increased, conflicts have increased, especially in areas outside the DMA (see figure 3) where habitat is not suitable for the bear's long-term viability.

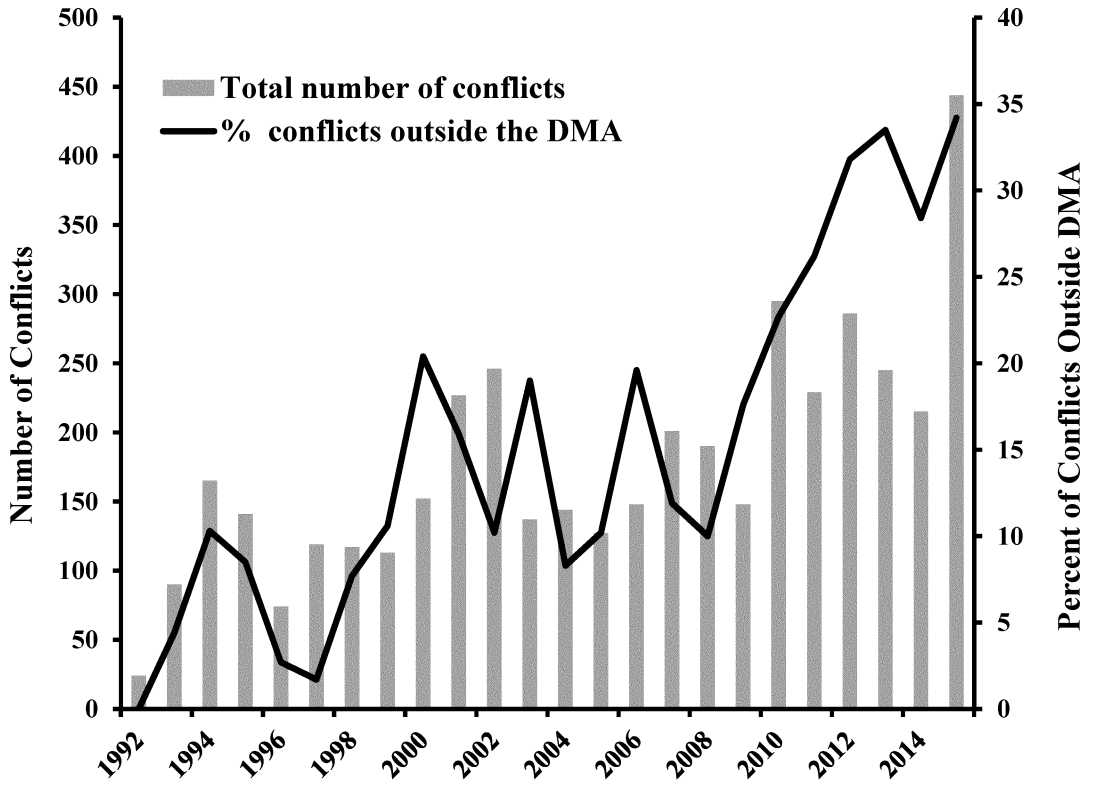

Figure 3. Number of grizzly bear conflicts compared to percent of conflicts outside of the DMA.

It is not unexpected that the number of conflicts would increase as bears increasingly encounter humans and livestock outside the PCA, where human access is generally greater than within the PCA. However, there is no evidence that bears are leaving the core of the ecosystem as a result of changes in food resources (see Issue 38 for further discussion). Areas with a high risk of grizzly bear mortality due to repeated conflict with humans or livestock were not considered suitable habitat and are not included in our quantification of habitat available to meet the needs of a recovered grizzly bear population (see Issue 40). The IGBST 2009 report (p. 3) identifies three main causes for increased known and probable mortalities, predation, hunting (defense of life and mistaken identity), and management removal as a result of cattle depredation. The States have invested considerable resources in hunter education to reduce mortalities as a result of mistaken identity and defense of life (see Issue 108 for further details). In addition, increased I&E efforts have been made to reduce attractants (YES 2016a, pp. 86–95). The IGBST maintains a database of known and probable GYE grizzly bear mortalities, including cause (see Issue 34). In addition, potential changes in verified conflicts will continue to be documented and evaluated, as well as annual evaluations of the population and mortality, and the YGCC can make modifications to the 2016 Conservation Strategy if they deem it is necessary to maintain a recovered grizzly bear population within the GYE.

We agree that nonlethal control of grizzly bears is the preferred option for managing human-bear conflict. However, no single management tool can resolve all issues associated with human-bear conflict. Therefore, State, Tribal, and Federal managers will continue to use a combination of management options, including nonlethal forms of management. The current methods we use to reduce human-caused grizzly bear mortality by preventing and addressing conflicts in a systematic, fair, and prompt manner have accommodated an increasing GYE grizzly bear population and range since 2002.

As previously noted, the 2016 Conservation Strategy identifies, defines, and requires adequate post-delisting monitoring to maintain a healthy GYE grizzly bear population, with clear State and Federal management responses if deviations occur. Agreed-upon total mortality limits will ensure that mortality will continue to be managed in accordance with recovery criteria. Notably, more than two-thirds of all suggested funding to implement the 2016 Conservation Strategy is designated to managing conflicts and conducting outreach to minimize conflicts, especially by decreasing attractants on private lands. Nonlethal means of addressing conflict such as relocation of conflict bears are included in the 2016 Conservation Strategy.

The 2016 Conservation Strategy prioritizes I&E programs to minimize human-bear conflicts. These programs work to change human perceptions, and beliefs about grizzly bears and Federal regulation of public lands. For example, hunter education courses and other educational materials strongly encourage hunters to carry bear spray, and information and education programs educate the public about potential grizzly bear attractants and how to properly store them. A stable to increasing GYE grizzly bear population, despite large increases in people living and recreating in the GYE over the last

three decades, is evidence of the success of programs implemented that will continue under the 2016 Conservation Strategy.

In addition to public I&E, the States have implemented programs to help reduce conflicts with people including: Livestock carcass removal, electric fencing subsidies for apiaries and orchards, and cost-sharing for bear-resistant garbage bins. Removal of conflict bears is still sometimes necessary. Removal is lethal to the individual bear, but it minimizes illegal killing of bears that might otherwise occur if people are encouraged to ''take matters into their own hands,'' and it thus serves a long-term conservation purpose. Bear removal also provides an opportunity to educate the public about how to avoid conflicts and thus limits removals in the future. It encourages tolerance of grizzly bears by responding promptly and effectively when bears pose a threat to public safety.

Human-grizzly bear conflicts are reported by jurisdiction in the IGBST annual reports. The IGBST continues to conduct research on many aspects of the GYE grizzly bear and their ecosystem. Problem bears are radio-tracked when they are relocated, and the IGBST plans to assess the efficacy of relocating problem bears in the near future. The lower survival rates of relocated bears suggests that relocation should be used conservatively; however, relocated female bears have contributed to the population and should be used as a viable management alternative to removal from the population (Brannon 1987, p. 572; Blanchard and Knight 1995, p. 564). The 2016 Conservation Strategy (YES 2016a, pp. 86–91) and the State management plans detail the conflict bear standards to be applied to the GYE grizzly bear DPS once delisted. Inside the PCA, grizzly bears will be given a higher priority whereas ''outside the PCA and National Park lands more consideration will be given to existing human uses.'' Conflict bear removals will be counted against the mortality limits set forth in this rule and the 2016 Conservation Strategy.

Issue 69—Public commenters asserted that the States' should prohibit black bear hunting within the DMA, or at the very least within the PCA, in order to reduce human-caused mortality from mistaken identification.

Response—The potential mortality that occurs to grizzly bears from mistaken identification is not considered a threat to the grizzly bear population. From 2007 to 2016, a total of 18 grizzly bear mortalities occurred in the GYE that were considered ''mistaken identity,'' of which only 2 were females. In 2008, five grizzly bears were reported as killed due to mistaken identification, prompting an evaluation of management and education strategies. The evaluation indicated that the increase in mistaken identity mortality was the result of bears expanding into new areas; therefore, outreach and education was increased. Following 2008, fewer than two grizzly bear mistaken identity mortalities per year were documented in the GYE. In Wyoming, black bear regulations (Wyoming Game and Fish Commission 2017, pp. 3–5—3–6) require that when a grizzly bear is detected at a black bear bait site, the hunter must shut down the bait site immediately and bear hunting at that site is disallowed for the remainder of the season. Baiting for black bears in Wyoming and Idaho is not allowed in the PCA and in the majority of the DMA and is not allowed statewide in Montana. The GYE grizzly bear population has increased while black bear baiting has been allowed in Idaho and Wyoming outside the PCA; therefore, we conclude that bear hunting is not a significant factor that will threaten the recovered status of the GYE DPS.

Issue 70—Commenters worried about the use of traps intended for game other than grizzly bears and the potential negative effects of these traps on grizzly bears, especially as grizzly bears' hibernation period shortens. Several commenters stated that trapping, as a means of harvest, should be prohibited for any animal within the PCA and/or the DMA to prevent the incidental take of grizzly bears. Several comments pointed out that the State plans do not have a reporting requirement or protocol if/when a grizzly bear is caught in a trap set for other game/nuisance species.

Response—Based on the best available information, we do not find any persuasive information to indicate that trapping for fur-bearing species will affect the viability of the GYE grizzly bear population. From 2002 to 2014, only one mortality occurred as a result of trapping for other game/nuisance species (Haroldson 2017b, *in litt.*). When we make our status determination of the GYE grizzly bear, we consider whether it is recovered and if State management will retain that recovered status if the Act's protections are removed. Harvest, irrespective of the method, is allowed at the States' discretion, contingent upon the harvest not exceeding the aforementioned mortality limits.

Issue 71—One commenter expressed concern that we did not adequately acknowledge the grizzly bear mortalities associated with the annual elk hunt in GTNP as a continuing threat. This commenter cited a recent court decision that allowed ''an increase in the number of grizzly bears that could be 'incidentally' killed in association with the annual elk hunt in Grand Teton National Park.'' Another commenter opined that we did not mention USDA Wildlife Services' incidental take of four grizzly bears since 1991.

Response—All known mortalities, including those associated with incidental take permits, such as the elk reduction program in GTNP, are included in the IGBST mortality database and, therefore, our mortality assessment. The mortality database identifies mortalities by cause and does note if mortality is associated with an incidental take permit. Grizzly bear mortality due to the elk hunt in GTNP is unlikely as only one grizzly bear mortality has occurred in the history of the elk reduction program in GTNP, and that was attributed to self-defense. GTNP now requires elk hunters to carry bear spray. Like any other mortality source, if there were a grizzly bear mortality associated with the annual elk hunt in GTNP, it would count against the maximum allowable mortality. The IGBST's calculation of unknown/unreported mortalities accounts for any unknown mortalities associated with incidental take permits. Mortality will continue to be managed within the mortality limits set forth in this final rule, the 2016 Conservation Strategy, and the Tri-State MOA.

The specific statement by the commenter about bears that could be incidentally killed is in regard to an ''Incidental Take Statement'' that is a projected potential mortality to grizzly bears that could occur within a project area, and rather is not something that is suggested or purported to occur. Regardless, Incidental Take Statements would no longer apply after the bear is delisted.

Issue 72—We received public comments asking that we discuss the trade of grizzly bear parts, including the extent of trafficking in the United States and the state of current legislation. The commenter suggested that States pass appropriate laws making such trafficking illegal. One commenter suggested that all grizzly bears remain listed until illegal harvest data is thoroughly evaluated.

Response—The Lacey Act of 1900 (16 U.S.C. 3371–3378) is a conservation law in the United States that prohibits trade in wildlife, fish, and plants that have been illegally taken, possessed, transported, or sold. Under the Lacey Act, it is unlawful to import, export, sell, acquire, or purchase fish, wildlife, or plants that are taken, possessed,

transported, or sold: (1) In violation of U.S. or Indian law; or (2) in interstate or foreign commerce involving any fish, wildlife, or plants taken, possessed, or sold in violation of State or foreign law. The law covers all fish and wildlife and their parts or products, plants protected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and those protected by State law. Commercial guiding and outfitting are considered to be a sale under the provisions of the Lacey Act and must comply with U.S. Federal and State law.

The Convention is an international treaty designed to regulate international trade in certain animal and plant species that are now, or potentially may become, threatened with extinction. Under this treaty, countries work together to regulate the international trade of species and ensure that this trade is not detrimental to the survival of wild populations. Species are listed in one of three Appendices to CITES, each conferring a different level of regulation and requiring CITES permits or certificates. Any trade in protected plant and animal species should be sustainable, based on sound biological understanding and principles. An Appendix I species is one ''threatened with extinction and provides the greatest level of protection, including restrictions on commercial trade.'' An Appendix II species is one ''although currently not threatened with extinction, may become so without trade controls.'' An Appendix III species is one for which a range country has asked other countries to help in controlling international trade. See *https://www.fws.gov/international/cites/index.html* for more information.

All international trade in brown bears is restricted by either CITES Appendix I (in parts of central Asia) or CITES Appendix II. All U.S. and Canadian populations are included in Appendix II. Even populations not at risk (*e.g.,* the population in Canada) is still regulated by CITES as it is a look-alike to those populations in Appendix I (including other species of ursids). Grizzly bear harvest under Appendix II for the purpose of international trade is also monitored via the issuance of CITES Export permits. Approved States and Tribes have procedures for placement of CITES export tags on skins (including furs and pelts) that were legally taken. The presence of a CITES export tag on a skin provides us with reasonable assurance that the skin was obtained legally and that hunters can legally export the item from the United States. We review the information we receive annually from each State or Tribe to determine if there is a need to reevaluate our State- or Tribe-based finding or if the species needs closer monitoring. In addition, the States work directly with us on issues related to illegal trafficking of bear parts and the States have assisted, and will continue to assist, us with all such Lacey Act investigations. Although harvest of grizzly bears for the purpose of illegal trade in parts for medicinal purposes still occurs to some extent, the best available information indicates that this activity is not occurring at a level affecting the GYE or any lower 48-State grizzly bear population, nor do we conclude it is likely to do so within the foreseeable future.

Issue 73—There were a number of comments from the public and peer-reviewers related to poaching, mistaken identity kills, and self-defense kills. Commenters expressed concern related to poaching, illegal take, mistaken identity kills, and self-defense kills. Commenters were either concerned that there would not be enough resources to investigate and prosecute poachers or that State penalties for illegal take (such as poaching), mistaken identity kills, and self-defense kills need to be more clearly articulated and more stringent. Commenters asserted that regulatory mechanisms require little to no action against hunters for mistaken identity kills (a product of the McKittrick Policy), and mistaken identity and self-defense kills should be prosecuted as illegal take to better deter illegal take of grizzly bears.

Response—After delisting, GYE grizzly bears will continue to be protected by State, Tribal, and Federal laws and regulations (see *Factors B and C Combined*), and enforcing agencies will continue to cooperate in the investigation of poaching incidents. There is no data that suggests that the jurisdiction under which poaching is prosecuted affects the willingness of poachers to commit the crime. We are aware of at least 22 intentional, illegal killings of grizzly bears in the GYE between 2002 and 2014, which constituted 7 percent of known grizzly bear mortalities during the same period. There is no evidence that illegal mortality levels increased following the 2007 delisting (GYE grizzlies were delisted from 2007 to 2009, before the delisting rule was vacated in *Greater Yellowstone Coalition* v. *Servheen, et al.,* 672 F.Supp.2d 1105 (D. Mont. 2009)). We do not expect poaching to significantly increase post-delisting because State and Tribal designation of the grizzly bear as a game animal means that poaching will remain illegal and subject to prosecution. The USFS, Tribal conservation officers, and Service special wildlife agents will continue to cooperate with State game wardens in the investigation of poaching incidents. Mistaken identification is prosecuted as illegal take, and any grizzly bear mortality is fully investigated to determine cause. Investigations of self-defense mortalities occur, and there have been instances of prosecution by the Service where the mortality was not deemed a self-defense situation. As previously stated, illegal take and self-defense related mortality count towards the total mortality limits within the DMA.

The McKittrick Policy requires proof of intent, that the individual knowingly killed a listed species under the Act, for Federal prosecution. However, intent is not necessary for prosecution under State law. During an investigation, the investigative officers usually meet with both local and Federal attorneys to decide if prosecution will be more successful under State or Federal jurisdiction. In most situations where the U.S. Attorney has declined prosecution conflicts, the States have taken over those prosecutions through State courts. There have been successful prosecutions under both Federal and State laws. For example, in 2015 a man knowingly shot at a grizzly bear in the Cabinet-Yaak ecosystem, was prosecuted in Federal court, and was sentenced to 6 months in Federal prison. Under Idaho State jurisdiction, a man was successfully prosecuted in a 2014 grizzly bear killing after making a false claim of self-defense and was assessed a penalty of a $1,400 fine and civil penalties ($500 of which was suspended), 30 days suspended jail time, 1 year revocation of his hunting license, and 2 years unsupervised probation. H.R. 4751, The Local Enforcement for Local Lands Act of 2016, was not enacted. And lastly, law enforcement officers cannot comment on ongoing cases; therefore, it is not appropriate to publicly share the details of grizzly bear mortalities that are under investigation.

Adequate Regulatory Mechanisms and Post-Delisting Monitoring Issues (Factor D)

Issue 74—Both peer-reviewers and public commenters expressed concern that the language in the *Factor D* section of the proposed rule was too non-committal. They requested we remove words such as ''may,'' ''anticipate,'' or ''expect'' if we hope to suggest a firm commitment to ensuring effective management post-delisting.

Response—Because modifications to State game regulations had not been

approved at the time the proposed rule was published, we were able to describe them only in conditional terms. Thus, we conclude that the terms ''anticipate'' and ''expect'' were used appropriately in this section of the proposed rule. However, prior to this final rule, State regulations have been finalized and are in place and will ensure the recovery criteria are met (*i.e.,* 2016 Conservation Strategy, Tri-State MOA, and State regulations).

Issue 75—A number of public comments questioned what we can legitimately consider an adequate regulatory mechanism and what plans, rules, regulations, and laws we can thus consider in our *Factor D* analysis (inadequacy of existing regulatory mechanisms). A number of commenters claimed that our analysis was flawed because it relied on management regimes that are outdated or not yet final (*e.g.,* the Idaho hunting regulations and the 2016 Conservation Strategy are still drafts; the Montana and Idaho grizzly bear management plans and the 2006 USFS Plan are outdated). One commenter asserted that it is not acceptable to simply state, ''standards and provisions not yet incorporated into management plans will be integrated into future land management plan amendments or revisions.'' These commenters emphasized that the analysis surrounding *Factor D* must be based on *existing* regulatory mechanisms; thus, we must have finalized State plans, State regulations, the 2016 Conservation Strategy, and MOA to consider in our final rule. One commenter asserted that ''adequate regulatory mechanisms'' not only must be final before delisting but must also be ''proven to be effective.''

Another commenter noted that YNP currently includes the outdated 2007 Conservation Strategy in its Superintendent's Compendium; this commenter requested additional clarity on whether the 2016 Superintendent's Compendium would incorporate the provisions in the revised 2016 Conservation Strategy. Other commenters questioned whether land use plans, State management plans, MOAs, and conservation strategies qualify as regulatory mechanisms since they are not binding and enforceable.

Response—In *Greater Yellowstone Coalition* v. *Servheen et al.,* 665 F.3d 1015 (9th Cir. 2011), the Ninth Circuit upheld the Service's determination that existing regulatory mechanisms were adequate. The Ninth Circuit reversed the Montana district court (*Greater Yellowstone Coalition* v. *Servheen et al.,* 672 F.Supp.2d 1105 (D. Mont. 2009)) on this point. The Ninth Circuit determined that the elements of the Conservation Strategy were incorporated into binding regulatory documents, specifically National Forest Plans and National Park Service Superintendents' Compendia. The Ninth Circuit noted this was of particular importance because the two agencies collectively manage 98 percent of the lands within the Primary Conservation Area. Further, additional wilderness protections applied to suitable grizzly bear habitat outside the PCA.

On-the-ground habitat protections for GYE grizzly bears have not changed since the 2011 decision, and the GYE bear population has stabilized. The NPS and the USFS continue to manage 98 percent of the land within the Primary Conservation Area. These regulatory mechanisms have been proven to be effective. The habitat management standards detailed in the 2016 Conservation Strategy (YES 2016a, pp. 54–85) to reduce human-caused mortality have already been implemented through National Park Compendia (YNP 2014b, p. 18; GTNP and JDR 2016, p. 3) and the 2006 Forest Plan Amendment (USDA FS 2006b, entire). Changes to both the Compendia and the Forest Plan amendments per the revised 2016 Conservation Strategy are considered minor and of little biological significance and, therefore, largely the same as previous regulatory mechanisms. For example, the method to measure motorized route densities was updated, based on the best available science, so that the moving window approach calculates the total route length instead of the previous method of absence or presence of motorized routes, which often over- or under-estimated total routes (for further details see YES 2016b, Appendix E). Both agencies are signatories to the 2016 Conservation Strategy, which means that current habitat management standards will be taken into account in decision-making and that human-caused mortality will be monitored and controlled.

Section 4(b)(1)(A) of the Act requires us to make listing determinations based on the best available scientific and commercial data after taking into account the efforts of States and foreign nations, whether through predatory control, protection of habitat and food supply, or other conservation practices. The Ninth Circuit did not determine whether the 2007 Conservation Strategy was a ''regulatory mechanism'' under *Factor D,* but the Service is still obligated to consider other conservation efforts in its listing determinations under the Act. The 2016 Conservation Strategy is such an effort.

In terms of regulatory mechanisms to manage mortality, we are confident that the GYE grizzly bear population will be managed according to the demographic recovery criteria set forth in the 2016 Conservation Strategy and agreed to by the States in their Tri-State MOA. This framework ensures that mortality from all sources will be monitored and controlled by the States to ensure consistency with recovery criteria. Idaho, Montana, and Wyoming have capably managed other big game species (*e.g.,* black bears, cougars), and we believe their respective State agencies have the resources, expertise, and incentives to continue their management responsibilities toward GYE grizzly bears if hunting is permitted in the future.

As to the comment that existing regulatory mechanisms must be both final and ''proven to be effective,'' please see our response above regarding the effectiveness of NPS and USFS. The Service's Policy for the Evaluation of Conservation Efforts when Making Listing Decisions is not applicable to delisting determinations (68 FR 15100, March 28, 2003).

Issue 76—Multiple commenters weighed in on the States' ability to appropriately manage grizzly bears. Commenters expressed distrust and claimed State management would be harmful or ineffective based on State ''mismanagement'' of other wildlife such as elk, bison, and large carnivores (*e.g.,* wolves). Commenters worried that the States may ignore management requirements and decision-making would be susceptible to political influence of special interests, and suggested that States may falsify mortality information to maximize the number of bears available for hunting.

Commenters supportive of State management expressed confidence in the States' commitment and abilities to maintain a recovered population of grizzly bears, and State management will be more nimble, efficient, adaptive, and responsive to local stakeholder needs than Federal management. The State agencies themselves, in addition to public commenters, expressed confidence in their abilities to maintain a recovered population of grizzly bears, citing financial and staffing commitments to do so.

Response—The States of Wyoming, Idaho, and Montana have invested tens of millions of dollars and dedicated considerable staff time to conserve and recover grizzly bears in the GYE. During this time the GYE population has increased to a point where it has stabilized within the DMA and is approaching carrying capacity.

Although commenters expressed concerns regarding the appropriateness of State management of grizzly bears, Wyoming, Idaho, and Montana have been managing and conserving wildlife since the early 1900s with significant increases in both ungulate and large carnivore populations. The States are committed to managing grizzly bears in accordance with the 2016 Conservation Strategy and its appended State grizzly bear management plans and regulations. By signing the Strategy, all management agencies have agreed to adhere to the demographic recovery criteria and habitat standards, including managing for connectivity for the foreseeable future, well beyond the delisting and the minimum 5-year monitoring period required by the Act to address the long-term need for continued coordination among signatory agencies (YES 2016a, p. 13). The State and Federal regulatory mechanisms meant to achieve those demographic and habitat standards are currently in place, and we have nothing in the record to suggest that those regulations will change within any calculable planning horizon.

Ongoing review and evaluation of the effectiveness of the Strategy is the responsibility of the State, Tribal, and Federal managers in the GYE and will occur at least every 5 years, allowing public comment in the updating process. Any significant departure from agreed-upon Federal and/or State management plans will trigger a status review, and, if data indicate that grizzly bears in the GYE are in need of protection under the Act, we can initiate listing procedures, including, if appropriate, emergency listing.

In response to concerns about the ordinances, regulations, or resolutions passed by county governments in Wyoming regarding the presence or distribution of grizzly bears in these counties, we requested a letter from the Wyoming Attorney General's office clarifying the authority of counties in Wyoming to legislate in the area of grizzly bear management. The Wyoming Attorney General's office's response, dated August 8, 2006, states on p. 2, ''`* * * as an arm of the State, the county has only those powers expressly granted by the constitution or statutory law or reasonably implied from the powers granted.' *Laramie Co. Comm'rs* v. *Dunnegan,* 884 P.2d 35, 40 (Wyo. 1994). Neither the Wyoming Constitution nor the legislature has provided the counties in Wyoming with any expressed or implied authority over management of grizzly bears. Therefore, counties lack the authority to enact any ordinances(s), regulation(s), or resolution(s) which would affect the (Wyoming Game and Fish) Commission's Grizzly Bear Plan on mortality or distribution of grizzly bears in Wyoming'' (Martin 2016, *in litt.*). This letter indicates that Wyoming county governments have no authority to enact laws that affect grizzly bear management commitments made by the Wyoming Game and Fish Commission.

Issue 77—A number of public commenters believed that the five requirements for State hunting regulations that we laid out in the proposed rule were inadequate, allow hunting regulations that are too liberal, and/or could have severe impacts on population viability because: (1) They gave the States too much latitude in bag limits, seasons, and sex ratios and age limits for grizzly bear hunting; (2) the definition of ''human safety purposes'' when deciding whether to allow additional grizzly bear mortality, and its distinction from human conflict, is unclear; (3) they do not adequately take mortality from ''unforeseen events, such as illness and natural disasters,'' into consideration; (4) they would allow for too many licenses to be issued; and (5) gaps in our regulatory requirements would not provide for adequate ecosystem-wide coordination and consistency in regulations. These commenters also suggested that the five requirements are insufficient to protect females and cubs because: (1) It would be difficult for the average hunter to distinguish between a male and female grizzly bear in the field or to tell the age of a grizzly bear; (2) they allowed for take of female grizzly bears and cubs; and (3) if a mother hides her cubs while she goes to find food, she will look like an independent female and will be vulnerable to take, leading to potential orphaning.

Commenters also suggested the Service require additional content in State regulations prior to proceeding with a delisting rule, such as that: (1) An ''independent panel of ecological researchers'' determine the total number of limited hunting permits; (2) managers use a lottery system to distribute these few licenses; (3) all three States require 12-hour reporting requirements as opposed to 24-hour reporting requirements; (4) establishment of prohibitions on the killing of any bear accompanied by other bears; (5) inclusion of provisions shutting down all hunting for the season once quotas for female grizzly bears are met; (6) States coordinate season dates through the YGCC and time seasons to minimize risks to females; (7) inclusion of provisions requiring proper food storage and handling of hunter-killed carcasses; (8) provision of subsidies for bear-proof garbage containers to increase affordability and use; and (9) State quotas should not change with intra-annual fluctuations in local population levels. On the other hand, another commenter suggested that the Service would fail to honor State wildlife laws if additional provisions are required in relation to grizzly bears.

The State agencies took issue with the fact that the proposed rule prematurely assumed the three States would establish hunting seasons and suggested that the Act does not ''require states to establish hunting seasons before delisting can occur.'' They thought that, by requiring specific provisions in State hunting regulations, the Service ''created a public expectation that hunting will occur as soon as delisting is finalized.''

Conversely, some commenters believed these five requirements were reasonable and adequate. These commenters referred especially to our fourth requirement as a key safeguard in ensuring the continued recovery of grizzly bears and preventing exceedance of mortality limits; this requirement ensures that the number of grizzly bears available for hunting fluctuates depending on the number of bears that have already died.

Response—We conclude, based on the best scientific and commercial data available, that the regulatory requirements we outlined in our proposed rule, and that the States incorporated into regulation, will maintain a recovered population of grizzly bears in the GYE. State fish and wildlife agencies have significant expertise in managing hunting in a sustainable way for multiple species, and, therefore, the Service did not feel the need to micromanage how States would implement hunting regulations beyond those issues discussed. We do not consider the hunting regulations in Montana, Wyoming, and Idaho to be too liberal, but rather the States have agreed to strict mortality limits, with the additional safeguard of subtracting any excess mortality in subsequent years, which will ensure the GYE grizzly bear population remains at healthy levels.

While State regulations include no prohibition on the taking of females or the taking of cubs, regulations do impose mortality limits on the numbers of females, males, and total bears taken, and prohibit the taking of female grizzly bears with dependent young. Mortality limits take into account all forms of mortality, including management removals, illegal kills, self-defense, calculated unknown/unreported mortalities, natural mortalities, and other causes such as vehicle collisions.

We believe this method adequately accounts for unforeseen mortalities.

Under State management, any open hunting season will be closed within 24 hours of the total mortality limit being met by Idaho and Wyoming (Idaho Fish and Game Commission 2016, p. 2; Wyoming Game and Fish Commission 2016, p. 67–2) and of the harvest limits being met by Montana (MFWP 2016, p. 4). If a hunter kills a female by mistake and causes an exceedance of the total allowable mortality limits for female bears, managers will subtract this mortality from the total allowable number of kills in the subsequent year, ensuring the number of female grizzly bear mortalities stays in check. Any reported cubs orphaned due to the human-caused mortality of the mother are counted as probable mortalities in the mortality database maintained by IGBST and will count towards the dependent mortality threshold. We conclude that the provisions outlined in the 2016 Conservation Strategy and the Tri-State MOA are adequate to ensure that the three States coordinate regularly to reconcile mortality statistics, plan appropriate conservation actions, adapt management, and generally ensure the continued recovery of grizzly bears in the GYE. Please see Issues 68 and 89, as well as *Factors B and C Combined* for a full discussion of mortality limits and States' harvest regulations.

We agree with States' comments that the Act does not require States to establish hunting seasons before delisting can occur, and we regret any false expectations our proposed rule may have established. However, our intent in requesting the hunting regulations prior to delisting was to clearly demonstrate adequate regulatory mechanisms that would ameliorate such a potential threat if the States chose to establish hunting seasons, and to ensure that the GYE grizzly bear population will remain recovered if States decided to implement hunting seasons. The willingness on the part of the three States to implement regulations prior to a final decision on their part to implement hunting seasons is further testament to their commitment to manage the species in a way to ensure it remains recovered post delisting.

Issue 78—Some of the commenters critical of State plans and management practices focused on the difficulties surrounding coordination of management between all the political entities in the GYE. Commenters worried that inconsistent management and lack of communication between the three State entities, Tribes, and Federal land managers would pose the biggest threat to grizzly bears after delisting, as it could lead to errors in allocation, insufficient or inconsistent enforcement, delays in shutting down hunting seasons, exceedance of mortality limits, violations of recovery criteria, inadequate reduction of discretionary mortality (when needed), population sinks, and lack of genetic connectivity. To mitigate this possibility, commenters requested: (1) Information on how the States would be sharing and comparing data about mortality and population levels; (2) a formal process for collaboration between the States and the NPS to coordinate the management of bears that live primarily on NPS lands; (3) a ''unified plan'' that takes into account how many bears the other States will take; and (4) additional detail in the 2016 Conservation Strategy describing the processes States will use to coordinate with each other. Conversely, one commenter suggested that entrusting the States with grizzly bear management will help State wildlife managers effectively and consistently manage all the wildlife species in their State as a complete and connected ecosystem.

Response—All monitoring, reporting results, and management actions are centralized under the YGCC and the IGBST, as described in the 2016 Conservation Strategy (YES 2016a, entire), which all the State and Federal agencies have signed and agreed to implement. The agencies responsible for managing the GYE grizzly bear population upon delisting came together to develop the 2016 Conservation Strategy and have been effectively cooperating and communicating with each other about grizzly bear management decisions for the last 35 years.

In *Greater Yellowstone Coalition* v. *Servheen et al.,* 665 F.3d 1015 (9th Cir. 2011), the Ninth Circuit upheld the Service's determination that existing regulatory mechanisms were adequate. The Ninth Circuit reversed the Montana district court (*Greater Yellowstone Coalition* v. *Servheen, et al.,* 672 F.Supp.2d 1105 (D. Mont. 2009)) on this point. The Ninth Circuit determined that the elements of the Conservation Strategy were incorporated into binding regulatory documents, specifically National Forest Plans and National Park Service Superintendents' Compendia. The Ninth Circuit noted this was of particular importance because the two agencies collectively manage 98 percent of the lands within the Primary Conservation Area. Further, additional wilderness protections applied to suitable grizzly bear habitat outside the PCA.

Since then the population has increased in abundance and distribution, and additional regulatory mechanisms have been adopted by State agencies to manage the GYE DPS at the ecosystem level, to ensure communication is facilitated annually to improve management, and to regulate any future hunting in a way that would ensure the species remains recovered. The Tri-State MOA (Wyoming Game and Fish Commission *et al.* 2016, pp. 5–6; YES 2016b, Appendix O) signed by the Commission and Directors of Wyoming, Idaho, and Montana defines the process by which the States will coordinate the management and allocation of discretionary mortality of grizzly bears in the GYE as follows:

- The Parties (referring to the three States) will support the IGBST in the annual monitoring of the GYE grizzly bear population.
- The Parties will meet annually in the month of January to review population monitoring data supplied by IGBST and collectively establish discretionary mortality limits for regulated harvest for each jurisdiction (MT, ID, WY) in the DMA, so DMA thresholds are not exceeded, based upon the following allocation protocol (YES 2016a, p. 46).
- The Parties will confer with the NPS and USFS annually. The Parties will invite representatives of both GYE National Parks, the NPS regional office, and GYE USFS Forest Supervisors to attend the annual meeting.
- The Parties will monitor mortality throughout the year, and will communicate and coordinate with each other and with Federal land management agencies as appropriate to minimize the likelihood of exceeding mortality limits.

It is true that States cannot compel Federal agencies to manage their lands in accordance with their State plans. However, as participants in the 2016 Conservation Strategy, both State and Federal agencies have agreed to carry out all its provisions, including the appended State plans. The Tri-state MOA directly incorporates the 2007 Conservation Strategy instead of the 2016 Conservation Strategy. The reason for this is that the MOA was signed before the 2016 Conservation Strategy was complete, but the MOA incorporates aspects of the 2016 Conservation Strategy. In addition, the MOA states that ''The Parties intend this MOA to be consistent . . . with revisions to these documents made in conjunction with the delisting process.''

Issue 79—Many commenters believed that the MOA, 2016 Conservation Strategy, and State regulatory mechanisms and management plans are ''inadequate'' to protect grizzly bears into the future and will not ''ensure a

stable, thriving, and connected grizzly bear population.'' One commenter expressed that, because of the history of wolf delisting and management, the public does not trust the Service's judgment in determining adequacy of State plans and regulations.

Commenters worried that no entity is required to act if States exceed mortality limits and that States are not compelled to monitor the grizzly bear population. To enhance enforcement of mortality limits, commenters suggested making the 2016 Conservation Strategy mandatory and not ''voluntary'' and instituting penalties for States if they ''exceed reasonable mortality thresholds.''

Many commenters provided detailed concerns about the content of regulatory mechanisms (though these concerns were not specific to any State regulation in particular). These included that: (1) Spring hunts are irresponsible since ''it is impossible to know how many bears will be killed later in the year through management removals, poaching, accidents or natural causes;'' (2) hunters would be able to kill hibernating grizzly bears due to provisions in the Sportsmen's Heritage and Recreational Enhancement (SHARE) Act of 2015; (3) States have not considered ''what to do with the wounded bears that will escape;'' (4) plans do not explain how the various entities will monitor mortality, revise limits, and prevent decreases in the levels of ''scientific oversight'' of the population; and (5) regulations lacked safeguards to prevent hunters, outfitters, or poachers from using radio collar frequencies to find collared bears.

One commenter suggested that the grizzly bear hunting regulations are too stringent and that normal licensing and hunting procedures should apply to any grizzly bear hunt (*i.e.,* hunts should be open to the public and non-resident hunters); this commenter thought that the hunts should not be special limited or controlled hunts. One commenter suggested that timing the hunt to minimize female mortality was not a legally binding requirement; this commenter also noted that creating such restrictions would be logistically challenging since denning times are highly variable with weather and food conditions and because males usually emerge from dens only 2 or 3 weeks earlier than females. Others shared general beliefs that the regulatory mechanisms were adequate, including: (1) That the proposed rule included ''every possible safety net, including triggers for relisting;'' and (2) that the States have committed to adjust mortality levels should populations fall below 675 bears and stop hunting if populations drop to less than 600 bears. The three States emphasized that they have agreed to collectively manage the GYE population at the ecosystem scale to maintain recovery through the Tri-State MOA. One State emphasized that the 2011 Ninth Circuit Court of Appeals ruling declared the regulatory mechanisms (which are still in place) to be adequate and thus any regulatory requirements beyond that framework are unnecessary.

Response—Comments specific to the adequacy of each State's individual regulations and plans, the MOA, mortality limits, and the 2016 Conservation Strategy appear in Issue 82. However, as noted earlier, State fish and wildlife agencies have significant expertise in how to sustainably manage game species. This expertise, combined with commitments made by States to manage the species for long-term stability, is evidence that the States will adequately manage grizzly bears to ensure the species remains recovered.

Issue 80—Many commenters stated that all State regulations (not just management plans) should require hunters to carry bear spray and should impose heavy fines or the threat of license revocation for those that fail to do so. Commenters noted that hunters are required to carry bear spray only in GTNP and JDR (though one State requested that we clarify that, since the JDR is not a NP, the bear spray requirement applies only in GTNP). In explaining the efficacy of bear spray, one commenter cited research from Smith *et al.* (2006), which found that 92 percent of bear attacks end when hunters use bear spray and 98 percent of those that carry bear spray left encounters with bears unscathed; conversely, when hunters use firearms for protection, they are injured 56 percent of the time and 61 percent of these encounters result in lethal removal of the offending bear (Smith *et al.* 2012).

Response—Although the States do not currently require hunters to carry bear spray, States demonstrate and promote the proper use of bear spray in hunter education courses and other educational venues and materials. While the proper use of bear spray is promoted by the States, it is not 100 percent successful at stopping attacks from bears. Therefore, implications that greater use of bear spray would result in ceasing mortalities of bears or people is inaccurate. For more information on hunter education and public information efforts, see Issues 67 and 108.

Issue 81—Commenters opined that our requirements for State regulations (and the regulations themselves) do not adequately regulate the manner or method of take (*e.g.,* baiting, use of hounds, trapping, stalking). Commenters suggested that a ban on all bear baiting be put in place in any area where grizzly bears could be present (not just inside the PCA) prior to delisting. Commenters expressed that bait stations pose threats to human safety, increase the risk of mistaken identity bear kills, and ''lure [bears] outside Park boundaries.'' These commenters noted that Montana, Idaho, and Wyoming treat bear baiting differently. Conversely, one commenter suggested that the Service should defer to the States on the practice of baiting.

Commenters also noted the need for bans on bear trapping and bear hunting with hounds in all three States (both within and outside the PCA) prior to delisting. Commenters worried that hunting with dogs leads to conflicts between dogs and grizzly bears and can attract grizzly bears to people. Commenters also expressed that trapping endangers humans and can cause severe damage to bears; this commenter asked if there is an Animal Care and Use Committee that has recently reviewed trapping in the GYE. One State suggested that a restriction on bear trapping should not be a foundation for grizzly bear delisting and that we remove the language in the rule that discusses bear trapping.

Response—We recognize and respect that many people find some or all forms of human-caused grizzly bear mortality as morally or ethically objectionable. However, the Act requires that we make our determination based on the status of the subject species (is it recovered and will State management retain that recovered status if the Act's protections are removed) and does not allow us to consider the manner in which individuals may be killed after delisting unless it would affect this overarching viability determination. The manner of take is subject to State control once grizzly bears are delisted. Based on the best available information, we do not find any persuasive evidence to indicate that the manner of killing will affect the viability of the GYE grizzly bear population. Protection of the GYE grizzly bear population and maintenance of the ecosystems on which bears depend has been, and will continue to be, managed consistent with the Conservation Strategy. Regarding baiting, Montana does not allow black bear baiting in any areas; black bear baiting inside the PCA is not allowed in Idaho or Wyoming (Servheen *et al.*

2004, p. 11). In areas outside the PCA in Idaho and Wyoming, State wildlife agencies will monitor grizzly bear mortality associated with black bear hunting and respond to problems if they occur. The GYE grizzly bear population has increased while black bear baiting has been allowed in Idaho and Wyoming outside the PCA, so we conclude that baiting is not a significant factor that will threaten the recovered status of the GYE DPS.

Issue 82—Commenters questioned what State mechanisms qualified as ''regulatory'' for purposes of the Service's *Factor D* analysis. Commenters challenged the adequacy of various individual State regulatory mechanisms, including the Tri-State MOA, individual State management plans, laws, and regulations, rules, proclamations, or other administrative mechanisms.

Commenters questioned whether each State had regulatory mechanisms that met the elements that we identified in our proposed rule as necessary for delisting if the States decide to establish hunting seasons. State agencies commented that the Service exceeded our authority by identifying these requirements before the States decided whether to establish hunting seasons.

Commenters claimed various State regulatory mechanisms were inadequate based on public notice or involvement, or because they were the subject of litigation. Commenters took issue with the contents of State regulatory mechanisms, claiming they did not explicitly limit discretionary mortality, they allowed preemptive or unlicensed killing of bears, or they allowed killing bears causing conflict with livestock. Commenters questioned the State Commission's qualifications to set management objectives and their commitment to honoring limits, claiming prior Commission actions had harmed grizzly bears or other wildlife, such as wolves and bison.

Commenters claimed that the Tri-State MOA was inadequate, stating that it was voluntary, did not reflect all revisions in the 2016 Conservation Strategy, or otherwise did not adequately monitor bears or limit mortality.

Commenters claimed that Idaho's proclamation was not a regulatory mechanism and that various aspects of Idaho's, Montana's, or Wyoming's hunting frameworks were not final. Commenters questioned the States' abilities to enforce hunting closures and violations. Commenters questioned the timing and location of potential hunts, including their relationship to National Park boundaries, cutworm moth sites, connectivity, vulnerability of cubs and attending females, vulnerability during other big game hunts, or bear movement between hunt areas.

Commenters claimed that Montana, Idaho, or Wyoming management plans were flawed because they contained outdated factual information, did not include recent science, did not include the most current population and mortality information, had inconsistencies with other documents, did not reflect all revisions in the 2016 Conservation Strategy, or did not fully commit to the 2016 Conservation Strategy. Commenters criticized Montana's plan for not supporting the State's claim of the importance of hunting for increasing human safety. Commenters criticized Idaho's plan for not mentioning the DMA. Commenters criticized Wyoming's management plan because its hunting fees were too low, because it had not defined the term ''human habituated'' to ensure that only those bears posing a safety risk (and not merely bears near developed areas) will be subject to removal, and because it had not explicitly described how it would deal with orphaned cubs. One commenter suggested Wyoming adopt a ''once-in-a-lifetime'' limitation for grizzly bear hunting.

Response—The Act requires the Service to base its listing decisions on the five factors set forth in 16 U.S.C. 1533(a)(1) and 1533(b)(1)(A). This includes Factor D, the inadequacy of existing regulatory mechanisms. Regulatory mechanisms are not defined in the Act, but they include those measures that, either individually or part of an overall framework, are designed to reduce threats to listed species or pertain to the overall State management and regulation of a listed species. The Act also directs the Service to consider other measures in its listing decisions, including ''those efforts, if any, being made by any State . . . to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices.'' (16 U.S.C. 1533(b)(1)(A)). The Service has a statutory obligation to take into account State conservation efforts, including the full range of State measures. This is part of the Service's Factor D analysis, and is consistent with other interpretations of the Act (*Defenders of Wildlife et al.* v. *Zinke et al.* 849 F.3d 1077 (D.C. Circ. 2017). The Service cannot dismiss a State conservation measure just because it is not legally binding. Rather, the varying levels of commitments and enforceability are taken into account as part of this analysis to ensure that the overall conclusion is reasonable. Here, the State statutes, regulations, and management plans, the 2016 Conservation Strategy, MOAs, and others reviewed in this rule all guide and clarify the States' approaches to grizzly bear management after desilting. All these measures are evaluated under Factor D and 1533(b)(1)(a). This includes the Tri-State MOA, which we consider under our broader statutory obligations under the Act, including 16 U.S.C. 1533(a)(1) and 16 U.S.C. 1533(b)(1)(A). We further note that the Tri-State MOA reflects the population goals set forth in the 2016 Conservation Strategy. This same conclusion applies to other mechanisms that commenters object to, including State management plans, policies, directives, and executive orders. Our review of the collective measures at issue is authorized under the Act, including the Act's legislative history, which indicates that section 4 listing or delisting inquiry was drawn broadly to allow the Secretary to determine whether a species is threatened or endangered (or recovered) for any legitimate reason. H.R. Rep. No. 93–412 (July 27, 1973). Our approach is also reasonable because ignoring any of these documents or aspects of State management would violate our responsibility under the Act to consider all factors relevant to determining the biological status of a species.

We reached the conclusion that State regulatory mechanisms are adequate to protect the recovered population of GYE grizzly bears and that they do contain the general elements we required in our proposed delisting rule. Our analysis is set forth in the final rule, and we refer commenters to that discussion under *Factors B and C Combined.* We also note that we provided the public with another opportunity to review the State mechanisms through our public notice and comment period described in 81 FR 13174, March 11, 2016.

To the extent that commenters objected to public notice and comment procedures utilized by the States in adopting their respective regulatory frameworks, we refer the commenters to the administrative procedural requirements that each State must follow under State law. Responding to the specific comment about Idaho's proclamations, we note that Idaho Fish and Game proclamations, orders, and director orders carry the force and effect of law under Idaho Code 36–105(3) and 36–106(6)(D).

As to the comment that hunting regulations are not final, we would not expect all State hunting regulations to be final because no decisions have been made to authorize hunting seasons in Idaho, Montana, or Wyoming. Furthermore, the process set forth in the

Tri-State MOA to establish discretionary mortality has not been undertaken yet because GYE grizzly bears have been protected by the Act. The allocation of discretionary mortality set forth in the Tri-State MOA must be followed before any State can identify a bear quota subject to hunting because it identifies how many bears, if any, exceed population objectives. Only after that process is completed can States set hunting seasons, establish hunt unit quotas for each unit, assess and define hunter eligibility requirements, set licensing requirements and fees, and other limitations specific to administering annual hunting seasons.

The States are governed by the Tri-State MOA and have agreed in writing to follow the 2016 Conservation Strategy. The Service's review of State actions is dependent on compliance with the regulatory measures required of each State (set forth in the proposed rule), and adherence to the population objectives in the Tri-State MOA and 2016 Conservation Strategy. Outside these requirements, States will have considerable latitude to design hunting seasons based on their own knowledge and expertise. The States have an incentive to manage bears based upon recovery criteria and the associated mortality limits in both the recovery criteria and the Conservation Strategy and are, therefore, expected to take into account the biological requirements necessary for successful management, including the locations of food sources, travel corridors, connectivity, NPS boundaries, etc. Recovery of the GYE DPS would not have occurred without the active participation, support, and leadership of Idaho, Montana, and Wyoming.

The Service has analyzed and reviewed State management of other species, like elk, deer, and black bears. Over decades, the States have demonstrated responsible and professional wildlife management of these species and have a proven track record of managing these and other species to population goals and unit targets. In the many discussions with our State partners, the Service has not encountered any situation or data that evidences an intent to deviate from these established wildlife management practices. This historical evaluation of other species informs the Service's conclusion that the suite of management principles and commitments can be reasonably considered in our overall delisting determination.

State management plans are useful because they help guide the State wildlife agencies in achieving management objectives, including population goals. The Service duly considers them in its analysis of a State's regulatory framework, as it is required to do under the Act. But management plans are not the only source of State management and control of wildlife populations. State management plans are just one of the many mechanisms the Service considered here. We understand that some commenters are disappointed that some State management plans for grizzly bears lack current data, but we look to other measures that are current and that will guide population management into the future. These include the State regulatory requirements, the Tri-State MOA, and the 2016 Conservation Strategy.

Issue 83—Many commenters weighed in on the process the Service and its partners used to author the 2016 Conservation Strategy, including: (1) That the negotiations about changes to the Conservation Strategy have been difficult to follow and the public does not know which changes have actually been incorporated into the final document (even though these changes could significantly alter grizzly bear management); (2) that the States could make changes to the Conservation Strategy at the eleventh hour when there is no risk of public scrutiny; (3) that the Service should be driving the process to revise the Conservation Strategy, not the States (as seems to be the case); and (4) since the Conservation Strategy is a change in management, it needs to be analyzed under NEPA, the National Forest Management Act, and the Act (including the drafting of an EIS). Another commenter pointed out that the draft 2016 Conservation Strategy we released with the proposed rule did not contain the Tri-State MOA, an agreement that has essential details necessary to evaluate the adequacy of the rule and 2016 Conservation Strategy.

Other commenters provided input on the content of the 2016 Conservation Strategy, in addition to the suggestions and concerns raised in other issues (*i.e.,* Issues 16, 17, 18, 19, 20, 31, 32, 40, 42, 43, 48, 49, 50, 53, 66, 68, 75, 78, 79, 84, 85, 86, 88, 89, 90, 91, 96, and 98), including: (1) Confusion as to who was responsible for preparing the Conservation Strategy and completing the tasks therein; (2) concerns that the Conservation Strategy does not adequately explain the process for revisions and adaptive changes (see Issue 91); (3) worries that it would be too expensive to keep radio collars on a minimum of 25 adult female grizzly bears in the GYE at all times in perpetuity (YES 2016a, Chapter 2); and (4) confusion as to why the Conservation Strategy requires States to collect and report data on the number of hunters if we suggest that there is no correlation between the number of hunters and grizzly bear mortality. One commenter worried about the implications of changes discussed at the October 3, 2016, YES meeting, namely: (1) Deletion of figures and description that explain when discretionary take would be permitted; and (2) removal of language explaining that 500 bears are necessary for genetic viability.

Commenters also suggested potential additions to the 2016 Conservation Strategy, including: (1) Reiteration of the five elements our proposed rule stated must be in State regulation; (2) inclusion of frequently cited documents (*e.g.,* Food Synthesis Report) in the Conservation Strategy Appendices; and (3) addition of a clear timetable for completion of the Strategy.

Response—The Administrative Procedure Act (APA) requires that final rules be a logical outgrowth of proposed rules, after taking into consideration new information and public comment. The final 2016 Conservation Strategy and this final delisting rule are logical outgrowths of the draft Conservation Strategy and proposed rule, both documents that were made available for multiple public comment periods and peer-review. Additionally, all YES meetings are open to the public, and meeting dates and locations are posted on the IGBC Web site (*http://igbconline.org/*).

Issue 84—Both public commenters and peer-reviewers raised concerns about the adequacy of funding moving forward to finance grizzly bear conservation, monitoring, and enforcement. A peer-reviewer stated that the draft rule is based on the assumption that sufficient Federal and State funds will be available into the foreseeable future ''to monitor and detect population changes with enough resolution to trigger management fallback mechanisms.'' Commenters worried that the MOA does not obligate any funds. Other commenters noted that implementation of the 2016 Conservation Strategy is dependent on funding, and one commenter suggested that the 2016 Conservation Strategy should require adequate funding to be ''fully procured'' for it to go into effect. Commenters and peer-reviewers also expressed confusion about the 2016 Conservation Strategy's discussion of funding (in Appendix F in the Draft 2016 Conservation Strategy), claiming it did not match the proposed rule nor adequately provide a formal outline for budgetary needs (though one peer-reviewer commended its inclusion).

Some commenters warned that Federal and State funding is not guaranteed and could decline at any time, potentially jeopardizing continued recovery.

Commenters expressed particular concern about the States' financial and administrative capacity to manage and monitor grizzly bears after delisting. Concerns about adequacy of State funding included: (1) A reminder that any Federal financial support would run dry after 5 years post-delisting; (2) confusion as to where States would find funds to make up this difference; (3) claims that delisting would cost an additional $1.2 million per year on top of current expenditures on recovery and would preclude States from pursuing certain funding opportunities (like Section 6 grants); (4) claims that funds generated from the sale of grizzly bear hunting licenses will not provide adequate funding to the States to manage grizzly bears; (5) worries that the Hicks Bill would relieve Wyoming of any obligation to pay to protect bears from illegal mortality; and (6) suggestions that States currently lack sufficient funds to combat poaching and this will only worsen in a delisted environment. Some commenters expressed concern that the States do not have sufficient staff to respond to hunting violations in a timely manner, close hunting seasons immediately upon meeting mortality thresholds, enforce adequate penalties on poachers, and conduct research and monitoring on grizzly bears to ensure effective adaptive management.

Commenters provided suggestions for ways to enhance confidence in State financial capacity for grizzly bear conservation, including: (1) State plans should clearly identify how they will fund grizzly bear monitoring, conservation, conflict management, and connectivity facilitation; (2) the Federal Government should provide sufficient financial support for State field biologists, State management of grizzly bears, and programs to minimize bear conflict; (3) decision-makers should develop a means to share tourism dollars with State wildlife managers; and (4) managers should revive the idea of an endowment fund for the 2016 Conservation Strategy and post-delisting management, which had been part of recovery and delisting discussions for more than 20 years.

Response—We conclude that combined State and Federal commitments will provide for adequate management of the GYE grizzly bear after delisting. Federal funding is dependent on year-to-year appropriations whether or not the species is listed.

The 2016 Conservation Strategy reflects the States' commitment to future management and monitoring of grizzly bears. The States have been funding and performing the majority of grizzly bear recovery, management, monitoring, and enforcement efforts within their jurisdictions for decades; for example, the WGFD has expended more than $40,000,000 for grizzly bear recovery from 1980 to 2015. There is not a reasonable basis to believe the States will not adequately fund grizzly bear management of a delisted population. Claims that it would cost an additional $1.2 million/year are not supported by empirical data.

On April 12, 2017, the Secretary of the Interior issued a Memorandum, ''Managing Grants, Cooperative Agreements, and Other Significant Decisions'' establishing a new review process for Wildlife and Sport Fish Restoration Program grants in the amount of $100,000 or more. This new process may affect States, however, we do not think this memorandum will affect the capacity to conduct grizzly bear post-delisting monitoring because these procedures are temporary and do not reduce the amount of funding available for assistance.

The best available information does not support commenters' claims that the States lack the ability to monitor, manage, and respond to violations as States' have long demonstrated their expertise in managing wildlife within their borders. For example, Idaho successfully prosecuted a violation for unlawful take of grizzly bears in the GYE under State law even while the grizzly bear was listed; see *State* v. *Sommer,* CR–2014–1601 (7th Dist. Idaho, 2014).

By signing the 2016 Conservation Strategy, participating agencies have committed to implementing the protective features that are within their discretion and authority, and to secure adequate funding for implementation. Lack of adequate funding to carry out the 2016 Conservation Strategy grizzly bear management commitments could trigger a status review for possible re-listing under the Act.

Issue 85—We received several comments on the adequacy of the Service's status review triggers and suggestions for revising them. The States requested that triggers be tied to evidence of a declining population, rather than those tied to a specific number of bears, exceedance of mortality limits, or particular regulations or management. Commenters also noted that the Service's triggers need to be standardized in the rule, the 2016 Conservation Strategy, and other management plans. We also received suggestions that ''a firm threshold for a review would be preferable to a 'may initiate' position.''

We received a few comments on the first Service Status Review trigger in the proposed rule, including: (1) It is unclear what ''significantly'' means in this trigger; (2) this trigger could reduce the ''flexibility that any management of any ecosystem requires'' by constraining the ability of States to update and adapt management plans and strategies; and (3) it is important to keep this trigger, despite State desires to remove it, ''so that future changes cannot lead to a decline in the grizzly bear population.''

Many commenters suggested increasing the population size in the second Service Status Review trigger so we would initiate a Service Status Review if the Chao2 population estimate fell below 600 bears in any given year. Other commenters suggested that the Service should determine whether the lower bound of the 95 percent confidence interval for the annual population estimate violates these requirements when assessing this trigger (as opposed to using the average).

Commenters also weighed in on the *third* Service Status Review trigger, expressing concern that this trigger could allow States to exceed mortality limits for several years before any review, ''allowing for irreversible damage;'' for example, it would allow States to exceed mortality limits in 7 out of every 10 years (as long as the years in which mortality limits are exceeded never occur three times in a row), pushing the population below 600 bears. Many commenters worried about the potential consequences of consistently exceeding mortality limits, and both commenters and peer-reviewers expressed concern that there will be a lag in a decision-making response to population declines that drop below 600, especially in high mortality years. As such, these commenters suggested changing the third trigger so that the Service would initiate a status review if the mortality limits for independent females are exceeded for two consecutive years and the population is below 600 bears.

Additional suggested triggers for a Service Status Review included those related to: A lack of funding; habitat standards/habitat degradation and monitoring protocols, including food monitoring (Johnson *et al.* 2004; Schwartz *et al.* 2010; Schwartz *et al.* 2012); population trends; lack of connectivity between the GYE and NCDE at least once during every 6-year period; and if the States classify grizzly

bears as a predator or vermin in the future (or any classification that allows for unlimited take).

Some commenters expressed concern about the meaningfulness of our triggers, whether the Service would be willing to re-list the grizzly bear, should it become necessary, and whether the Service could re-list in a timely manner before populations decline further (given the usually lengthy process required for a listing determination). Some commenters expressed concern that the triggers do not require the Service or any other parties to act if they are violated. One commenter suggested that re-listing should be automatic to avoid these delays or failures to act. One commenter asked what recourse the Service had if other agencies did not abide by the agreements. One commenter asked how the Service would determine whether a status review is ''warranted'' if an individual, organization, or YGCC were to petition for such a status review. Another commenter warned that the Service cannot use ''the possibility of relisting as a justification for delisting,'' based on past court decisions.

Response—The triggers for status reviews have been standardized between the 2016 Conservation Strategy, the Service's recovery criteria, and this rule. In addition, this rule uses ''would'' and ''will'' to confirm the firm threshold for review.

In response to comments on the *first* status review trigger, we would consider any changes in Federal, State, or Tribal laws, rules, regulations, or management plans to be a significant threat to the population if they would not maintain a recovered population. As stated in this final rule and the 2016 Conservation Strategy, this scenario does not inhibit adaptive management and application of the best-available science.

In response to comments on the *second* status review trigger, we believe that conducting a status review if the population estimate is less than 500 in any given year is appropriate. If any annual population estimate is less than 600, then discretionary mortality would cease, except for cases of human safety, thus reducing mortality rates. This approach allows appropriate corrective management responses by the management agencies to allow the population to increase prior to a status review. See Issue 19 for further discussion.

In response to the comments on the *third* status review trigger, this trigger was removed from the 2016 Conservation Strategy and this rule. However, the Service may choose to conduct a status review at any point that it deems there is a threat to the recovery of the GYE grizzly bear population or in response to any petition to re-list from an individual or organization that is determined to be substantial. Therefore, if mortality limits are exceeded repeatedly, the Service may choose to conduct a status review regardless of the population estimate.

In response to the comments requesting for additional triggers based on habitat or food monitoring, we consider the establishment of habitat thresholds for food sources to be unrealistic. As discussed in Issue 99, due to the natural annual variation in abundance and distribution in the four major food sources, there is no known way to calculate minimum threshold values for grizzly bear foods. The 1998 baseline will address these issues adequately through access management and limitations on site development. Managers will use an adaptive management approach that addresses poor food years with responsive management actions such as limiting grizzly bear mortality, increasing (I&E) efforts, and long-term habitat restoration (*i.e.,* revegetation, prescribed burning, etc.) as appropriate. The multiple indices used to monitor both bear foods and bear vital rates provide a dynamic and intensive data source to allow the agencies to respond to potential problems. We conclude that the adaptive management system described in the 2016 Conservation Strategy (YES 2016a, pp. 33–85) is one of the most detailed monitoring systems developed for any wildlife species and ensures the maintenance of a recovered grizzly bear population in the GYE.

The multiple indices used to monitor both bear foods and bear vital rates provide a dynamic and intensive data source to allow the agencies to respond to potential problems. The monitoring and adaptive management system described in the 2016 Conservation Strategy (YES 2016a, entire) ensures the maintenance of a recovered grizzly bear population in the GYE.

We agree that the mere possibility of re-listing is not an adequate regulatory mechanism. Re-listing cannot be an automatic function if the GYE grizzly bear population declines to the point where the protections of the Act become necessary because we are obligated to conduct rulemaking procedures, which include, among other things, an evaluation of threats as outlined in the Act and the APA. However, listing may be expedited if necessary through the Act's emergency listing procedures. Be that as it may, we remain confident that these provisions will not be necessary due to the species' current and foreseeable viability, as managed and monitored by the 2016 Conservation Strategy and Tri-State MOA.

Issue 86—Commenters expressed concerns about the triggers for an IGBST Biology and Monitoring Review, including: (1) Confusion as to the justification for changing the Biology and Monitoring Review trigger from its current status (mortality limits exceeded for any sex/age class for 2 consecutive years) to 3 consecutive years and a population floor; (2) assertions that failure to meet recovery criteria should trigger a status review and emergency re-listing rather than a review by the IGBST; (3) concerns about the lack of a defined timeframe for completion of a review report and remedying the identified issues; (4) suggestions for clearer Service responses should the YGCC fail to take appropriate action in response to a review; (5) suggestions that the Biology and Monitoring Review triggers need to be standardized in the rule, the 2016 Conservation Strategy, and other management plans; (6) claims that the triggers are too low or are unclear; (7) concerns that there is no trigger for a lack of funding; (8) worries that a review would be politically influenced; and (9) recommendations that the delisting rule provide ''clear thresholds and corrective mechanisms'' with a process that ''a. ensures timely action and limits time lags that arise from administrative review; b. includes an opportunity for public involvement in proposed actions, and; c. establishes a policy of rejecting proposed actions, if not supported by the best available science.''

Response—Edits were made to all three documents to clarify the triggers for an IGBST Biology and Monitoring Review and to make them consistent between the documents. The triggers for an IGBST Biology and Monitoring Review are based on the demographic recovery criteria and are believed by managers to be effective for decision-making given available data. Proposed triggers for an IGBST Biology and Monitoring Review are designed to be sufficient to detect meaningful demographic changes in a timely manner. More importantly, triggers for an IGBST Biology and Monitoring Review can be adjusted if the IGBST deems they are not sufficiently sensitive or, in contrast, too sensitive (*i.e.,* causing many ''false triggers''). The IGBST Biology and Monitoring Review triggers are more easily activated than Service review triggers to supply the YGCC with ample time to respond with management actions if necessary. It would be more appropriate to tie any lack of funding for the IGBST's

monitoring responsibilities to a decision by YES/YGCC to address the issue. Details were added to this rule and the 2016 Conservation Strategy that a Biology and Monitoring review would be completed within 6 months of the request by the YGCC and the resulting written report would be presented to the YGCC and made available to the public. Any proposed changes to the 2016 Conservation Strategy by the YGCC, in response to a Biology and Monitoring Review, to address deviations from the population or habitat standards will be available for public comment and be based on the best available science.

Issue 87—Commenters and a peer-reviewer suggested that the IGBST should give a binding commitment to conduct a demographic monitoring review every 5 years or less (instead of every 5 to 10 years) because: (1) It would be more consistent with precautionary management; (2) the generation length for grizzly bears is close to 10 years; and (3) the IGBST could miss dramatic shorter term changes in grizzly bear populations in an interval of 5 to 10 years between reviews.

Response—The best available data indicate that 5 to 10 years is an appropriate interval to conduct a monitoring review. For example, generation times are now actually closer to 14 years (Kamath *et al.* 2015, p. 5516), further supporting the frequency of 5 to 10 years. Grizzly bears are a long-lived species, and estimated survival rates for both independent males and females in the GYE are over 95 percent annually until age 25, when survival begins to decline. Any demographic review done with shorter intervals will likely have many of the same individual bears in the sample. The longer the interval between assessments the more likely it is we will have different individuals in the sample. This greater independence among bears in the sample is desirable if we are trying to assess impacts of landscape change on the demographic vigor of the population.

While official reviews will be conducted only every 5 to 10 years, the IGBST will closely monitor the population annually, including estimating population size using the model-averaged Chao2 method, monitoring and reporting the distribution of reproducing females, and monitoring and reporting mortalities. Habitat variables will also be monitored annually, including livestock grazing, food availability, and ungulate populations, Yellowstone cutthroat trout, moth aggregation sites, and whitebark pine cone production and health. The IGBST could at any time recommend a Biology and Monitoring Review to the YGCC if they deem necessary based on annual monitoring results. Additionally, the Strategy outlines specific triggers for an IGBST Biology and Monitoring Review as well as a Service-initiated status review.

Issue 88—One commenter raised concerns that managers would not be able to effectively implement adaptive management because there is no commitment to funding and implementing the necessary monitoring. Grizzly bear managers have failed to implement adaptive management in the past; for example, they did not redefine the Recovery Zone even though 40 percent of occupied habitat is now outside of it.

Many commenters and a peer-reviewer requested additional information on the adaptive process for revising the 2016 Conservation Strategy during its duration should the best available science indicate changes are warranted. One commenter hoped authors could include specific provisions in the 2016 Conservation Strategy requiring review and updating every 5 years or including language in the preamble explaining that the 2016 Conservation Strategy will evolve as new science becomes available.

Response—We have no reason to conclude that State, Tribal, and Federal land managers are not committed to fund and implement monitoring (see Issue 84). Given that the grizzly bear generation time is more than 5 years and long-term data is needed to determine meaningful trends, it is appropriate that the IGBST has adopted an adaptive management process; the purpose of adaptive management is to change based on improving science. Recovery plans are not regulatory documents, rather they are intended to provide guidance to the Service and our partners on methods to minimize threats to listed species and on criteria that may be used to determine when recovery is achieved. In response to the comment that we have failed to implement adaptive management by not updating the Recovery Zone in the Recovery Plan, delisting determinations are based solely on an evaluation of the five factors under section 4 of the Act, and, while recovery criteria can inform that analysis, we do not need to update a species' recovery plan prior to the species' delisting. In accordance with the 1993 Recovery Plan, Recovery Zones are areas large enough and of sufficient habitat quality to support a recovered grizzly bear population and are not designed to contain all grizzly bears in the ecosystem.

Issue 89—Public commenters presented differing perspectives on whether the content of the proposed rule represented an overreach of Service authority or too little Federal Government involvement. The State agencies called some of the content of the proposed rule (particularly demands about the content of State hunting regulations and the discussion of connectivity and movement of bears between ecosystems) ''unduly prescriptive'' and suggested that some of the requirements in the proposed rule ''transcend the Act's authority.'' Some commenters and the States questioned whether we had the authority to require particular hunting regulations prior to delisting, while others suggested that we require States to classify grizzly bears as a non-game species, thus, prohibiting hunting altogether. One commenter suggested that States should be the ones setting mortality limits and monitoring mortalities.

Commenters also varied in their perspective on the proper Service role after delisting. Some commenters suggested the Service should have little to no role after delisting; one stated that after delisting ''the Service must monitor, but not dictate, the state's or Tribes' management methodologies.'' One commenter requested that we clarify that the 2016 Conservation Strategy is a cooperative agreement and that the Service's role is not to oversee management but to evaluate the five factors under the Act should it be necessary. Others suggested the proposed rule did not allow enough Federal involvement after delisting and urged more Service engagement in independent monitoring. Some commenters went so far as to suggest ''management should continue to be the responsibility of the USFWS'' and that the Service should use the preemption clause of the Constitution to invalidate any State or local laws that jeopardize grizzly bears. Another commenter simply requested that we explain and clarify the Service's role in grizzly bear management within the GYE after delisting.

Response—A basic tenet of wildlife management in the United States is that States have primary jurisdiction over most wildlife in most cases. The Federal Government has a ''trust resource'' responsibility for a few specific categories identified under Federal law, including species deemed threatened or endangered under the Act. When a species no longer qualifies as threatened or endangered, the management reverts back to the States.

Under the Act, we are required to show that threats to listed species have

been sufficiently abated (and will remain so for the foreseeable future) such that we can reasonably reach the conclusion that the species is no longer threatened or endangered. Section 4(b)(1)(A) further clarifies that we are to take into account those efforts being made by any State to protect such species. Under Section 4(a)(1)(d) of the Act, we must determine whether it is endangered or threatened because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. The 2016 Conservation Strategy and the corresponding step-down State and Federal regulations implementing this agreement are necessary to illustrate how various risk factors are going to be managed and allow us to determine that threats have been sufficiently abated such that the species is no longer threatened or endangered.

For grizzly bears, our analysis under *Factors B and C Combined and D* identifies human-caused mortality and the regulations governing it as crucial determinants of whether grizzly bear populations in the GYE will meet the definition of an endangered or threatened species. This is similar to our previous assessment of habitat (*Factor A*) and its long-term management (*Factor D*), which was previously litigated and upheld on appeal. Therefore, regulatory mechanisms that adequately address management of discretionary mortality are a necessary component of the path to delisting. It remains the Service's statutory responsibility to analyze threats to the species under the five listing factors and evaluate whether such regulations are consistent with a delisting determination under the Act. The State, Federal, and Tribal partner agencies implementing the 2016 Conservation Strategy continue to work together to implement a regulatory framework that allows grizzly bears in the GYE to be recovered and delisted under the Act, with continuing habitat and population management under the authorities of the individual agencies. Thus, this final rule describes standards for evaluating whether State game regulations are consistent with grizzly bear mortality targets, under the management framework of the interagency 2016 Conservation Strategy. The authority for promulgating hunting regulations for game animals remains with State wildlife commissions.

We conclude that the Service's involvement in grizzly bear management, as described in this final rule, is appropriate in scope and is consistent with statutory requirements. After the delisting of grizzly bears in the GYE, the regulatory protections of the Act will be withdrawn but the Service will continue to evaluate the species' status through post-delisting monitoring as described in the interagency 2016 Conservation Strategy. Post-delisting monitoring will continue to include data collected by various State, Tribal, and Federal agencies under the 2016 Conservation Strategy; we are confident that such monitoring can continue to provide valid data on grizzly bear status, and conclude that monitoring programs do not need to be funded and implemented separately by the Service. Because grizzly bears are vulnerable to excessive human-caused mortality, the 2016 Conservation Strategy recognizes the need for active management under the jurisdiction and authority of the various Federal, State, and Tribal agencies to implement conservation measures intended to address the source of such mortality.

With continuing interagency cooperation in implementing the 2016 Conservation Strategy, we fully expect partners will maintain healthy grizzly bear populations in the GYE without the protections of the Act. As is the case for any non-listed species, the Service can conduct a status review at any time and is required to consider petitions for re-listing if ever received. Such a review will be triggered if population and mortality targets in the 2016 Conservation Strategy are consistently not met. Furthermore, although we conclude this will likely not be necessary, Section 4(g)(2) of the Act directs the Service to make prompt use of its emergency listing authority if necessary to prevent a significant risk to the well-being of the recovered population.

We anticipate that the Federal Government will continue to be involved in grizzly bear management after delisting. As discussed in the proposed rule, the NPS, USFS, and BLM are responsible for land management over much of the GYE, and will continue to be actively involved in interagency groups implementing the 2016 Conservation Strategy. Similarly, Federal scientists, such as those employed by the USGS, will continue to monitor the GYE grizzly bear population. The Service plans to remain informed about grizzly bear status and population trends, and to remain engaged with partners as the 2016 Conservation Strategy is implemented.

As discussed in the proposed rule, we conclude that limited and well-regulated harvest of grizzly bears can be compatible with meeting mortality targets under the 2016 Conservation Strategy, and thus maintaining a healthy population that does not require the Act's protections. The suggestion to designate grizzly bears as non-game and prohibit regulated harvest altogether is not necessary, nor is it within Federal control for most unlisted species. For example, brown bear hunting is a common and sustainable practice globally. When managed correctly, as discussed in the final rule, carefully regulated harvest can be a part of the greater conservation strategy.

Issue 90—A number of public commenters expressed concern about our use of the term ''conservation reliant'' species in reference to grizzly bears.

Response—We no longer use the term ''conservation-reliant species'' in this rule.

Issue 91—Public commenters presented differing points of view on the implementation period of the 2016 Conservation Strategy. Some parties (including the States) took issue with our characterization of the 2016 Conservation Strategy in the proposed rule as being indefinite or being in place in perpetuity. These commenters suggested that an overly long post-delisting monitoring period impinged upon States' rights. They expressed the concept that the Act is an emergency room statute and that once a species is recovered its management should be returned to the States without Federal oversight. Some commenters (including the States) suggested that the Service has conflated ''conservation-reliance'' with post-delisting management that exceeds the Act's requirements and that the Conservation Strategy should not be an indefinite agreement to allow for more flexibility in adjusting management strategies in response to future change. One commenter argued that the Act does not require a 2016 Conservation Strategy for delisting. A number of commenters suggested the 2016 Conservation Strategy should stay in place only for the minimum 5-year monitoring period the Act requires. The States asked the Service to remove any mentions of the 2016 Conservation Strategy being in place ''in perpetuity,'' ''perpetually,'' or ''indefinitely'' and instead state that ''[t]he 2016 Conservation Strategy will remain in effect beyond the 5-year monitoring period of the Act.''

Others suggested the 2016 Conservation Strategy should stay in place for much longer than 5 years. One commenter recommended a post-delisting monitoring period of 18 years based on grizzly bears' slow reproduction and vulnerability to habitat change, noting previous precedents for monitoring periods up to 20 years. One commenter stated that ''it is critically important that the IGBST continue to be involved'' with GYE grizzly bear recovery GYE for 10 or more years after delisting. Several commenters expressed that the Conservation Strategy should be in place ''in perpetuity.''

Other commenters referenced revisions to the 2016 Conservation Strategy that clarify how it would remain in effect for the ''foreseeable future.'' In light of the above, commenters requested that we clarify how long the 2016 Conservation Strategy would remain in effect, how long monitoring would continue, and what would happen after that point. One commenter requested a definition of ''foreseeable future.'' Another commenter stated that common usage for ''foreseeable future'' was 100 years, similar to the timeframe of a forest rotation, and recommended monitoring over two rotations to allow their effects to manifest. Another commenter agreed that management was required over the foreseeable future because the grizzly bear is a conservation-reliant species.

Response—The 2016 Conservation Strategy serves as our post-delisting monitoring plan and represents the agreement from all management partners on post-delisting management. Post-delisting monitoring refers to activities undertaken to verify that a species delisted due to recovery remains secure from risk of extinction after the protections of the Act no longer apply (USFWS and NMFS 2008, p. 1–1). The primary goal of post-delisting monitoring is to monitor the species to ensure the status does not deteriorate, and if a substantial decline in the species (numbers of individuals or populations) or an increase in threats is detected, to take measures to halt the decline so that re-proposing it as a threatened or endangered species is not needed (USFWS and NMFS 2008, p. 1–1).

Section 4(g), added to the Act in the 1988 reauthorization, requires the Service to implement a system in cooperation with the States to monitor for not less than 5 years the status of all species that have recovered and been removed from the list of threatened and endangered plants and animals (USFWS and NMFS 2008, p. 1–1). The legislative history of section 4(g) indicates that Congress intended to give the Services and States latitude to determine the extent and intensity of post-delisting monitoring that is needed and appropriate (USFWS and NMFS 2008, p. 1–1). According to our 2008 Post-Delisting Monitoring (PDM) Plan Guidance, decisions regarding frequency and duration of effective monitoring should appropriately reflect the species' biology and residual threats (USFWS and NMFS 2008, p. 4–4).

Delisting criteria and the formal rulemaking process for removal from the list are designed to provide reasonable confidence that the species will remain secure for the foreseeable future, and post-delisting monitoring provides an additional ''check'' on projections that the species will remain secure after removal of the Act's protections (USFWS and NMFS 2008, p. 4–3). There are no absolute guarantees against future declines, but if the species appears to remain secure, conclusion of post-delisting monitoring is appropriate (USFWS and NMFS 2008, p. 4–3).

We agree that it is unrealistic and is beyond what is required by the Act to expect any single version of the Conservation Strategy and intensive Federal oversight to remain in effect in perpetuity. Therefore, the 2016 Conservation Strategy was revised to remain in effect for the foreseeable future as this is the time horizon that we must consider as we evaluate the species' status relative to the Act's definition of a threatened species.

In making our determination, we considered what the ''foreseeable future'' means in the context of GYE grizzly bear biology and the factors potentially affecting bear viability. To determine whether a species is likely to become endangered in the foreseeable future, the Service must consider the period over which it can make reliable predictions. It cannot speculate. Solicitor's Opinion M–37021, *The Meaning of ''Foreseeable Future'' in Section 3(20) of the Endangered Species Act* (2009). Consideration of the foreseeable future often involves determining when current or future trends cannot be further extrapolated without veering into speculation. It can also involve making reliable predictions about future events. Using the best scientific and commercial information available, the Service must analyze events, trends and threats over different periods of time, and must synthesize that information to reach a final conclusion about GYE grizzly bears.

The partners managing the GYE grizzly population have, as discussed above, successfully reduced or eliminated the negative trends that led to the listing of the bear in the first place. In addition, we anticipate no particular future events that will lead to the DPS becoming in danger of extinction in the future. Future implementation of the 2016 Conservation Strategy and its management objectives have also been expressly tied to the statutory concept of the foreseeable future. Under these circumstances, with a stable and protected population extending into the indefinite future, there is no need to more precisely define a particular period as being the ''foreseeable future'' for the bear. In other words, we cannot reliably predict on any human timescale that the status of the bear will deteriorate at all, much less that it will become in danger of extinction in the future.

However, there is not an expectation that the 2016 Conservation Strategy will remain static during its lifespan. In fact, the YGCC (the body that will coordinate management and promote the exchange of information about the GYE grizzly bear population after delisting) can revise or amend the 2016 Conservation Strategy based on the best biological data and best available science (YES 2016a, chapter 6). Any such amendments will be subject to public review and comment and approved by YGCC (YES 2016a, p. 96). More meaningful changes will need to be evaluated by the Service to determine whether they would depart significantly from previous commitments or represent a significant threat to the population and thus trigger a status review.

Periodic status reviews are consistent with Service practice for other species. For example, the Service has a history of conducting such reviews during the Northern Rocky Mountain gray wolf post-delisting monitoring period. Specifically, during this 5-year post-delisting monitoring period, we conducted six annual evaluations of status (in their entirety: Bangs 2010, *in litt.;* Jimenez 2012, *in litt.;* Jimenez 2013a, *in litt.;* Jimenez 2014, *in litt.;* Jimenez 2015, *in litt.;* Jimenez 2016, *in litt.*) and seven ''on-the-spot'' evaluations considering whether some of the more meaningful changes to State management laws or regulations met that standard (Cooley 2011, *in litt.;* Cooley 2012, *in litt.;* Jimenez and Cooley 2012, *in litt.;* Sartorius 2012, *in litt.;* Jimenez 2013b, *in litt.;* Cooley 2013, *in litt.;* Cooley 2014, *in litt.*). In those cases, wolf biology, high population levels and a demonstrated track record of withstanding high levels of human-caused mortality provided us with

sufficient confidence that the changes did not represent a significant threat and did not trigger a Service status review.

Issue 92—One commenter expressed concern that we do not discuss the BLM's sensitive species program in the proposed rule. This commenter wanted us to describe ''how grizzly bears will be classified for planning and management purposes on BLM lands post-delisting.'' Several commenters stated that the BLM must have regulatory mechanisms in place to protect grizzly bear habitat after delisting, provide connectivity between habitats, and ensure adequate habitat protections are in place; commenters were concerned that these mechanisms were missing or remained in drafts unavailable to the public.

Response—Upon delisting, the GYE grizzly bear will be classified as a sensitive species by the BLM for at least 5 years. A sensitive species is one ''requiring special management consideration to promote their conservation and reduce the likelihood and need for future listing under the ESA'' (BLM 2008). All land use and implementation plans must address the conservation of sensitive species through appropriate habitat management. Twenty-two percent of suitable habitat outside of the PCA is managed by the BLM. This information and the habitat protections provided by this designation have been added to both this final rule (see *Factors A and D*) and the 2016 Conservation Strategy (YES 2016a, pp. 115–116).

Issue 93—We received some comments from peer-reviewers and the public in reference to the USFS designation of the grizzly bear as a ''sensitive species'' or ''species of conservation concern'' upon delisting. Commenters and one peer-reviewer considered this USFS designation an important component of ongoing management of grizzly bears. Some commenters asked for specific statutory and regulatory definitions for ''sensitive species'' and ''species of conservation concern'' and the amount of protection afforded under each designation. Commenters expressed concern about the different authority these USFS designations provide and worried that the new designation of ''species of conservation concern'' under the 2012 Planning Rule would not provide the same project-level prohibitions as the ''sensitive species'' designation.

Response—The inherent protections afforded by the Sensitive Species designation and the Species of Conservation Concern and the Individual Species Direction are comparable. All three are designed to meet the intent of the USDA Departmental Regulations 9500–4, which directs the USFS to ''Avoid actions which may cause a species to become threatened or endangered'' and Sensitive Species Objectives (USDA FS 2005, Manual 2670.22), which include: ''Develop and implement management practices to ensure that species do not become threatened or endangered because of USFS actions and ''Develop and implement management objectives for populations and/or habitat of sensitive species.'' Following are the regulatory definitions:

Sensitive Species: Those plant and animal species identified by a regional forester for which population viability is a concern, as evidenced by: (1) Significant current or predicted downward trends in population numbers or density; and (2) Significant current or predicted downward trends in habitat capability that would reduce a species' existing distribution. (USDA FS 2005, Manual 2670.05).

Species of Conservation Concern: For purposes of this subpart, a species of conservation concern is a species, other than Federally recognized threatened, endangered, proposed, or candidate species, that is known to occur in the plan area and for which the regional forester has determined that the best available scientific information indicates substantial concern about the species' capability to persist over the long-term in the plan area. (36 CFR 219.9(c)).

Issue 94—Some commenters were concerned with the Service's portrayal of the USFS designations of Wilderness, WSA, and IRA and the protections each of these areas provide. Some felt that these designations are not restrictive enough to assume that there will be no impact on grizzly bears living in those areas. In roadless areas, energy development or road construction can occur in conjunction with oil and gas leases that pre-date the effective date of the roadless rule. In addition, roadless areas allow for off-road vehicle use, motorized ATV trails, and human recreation, which may impact habitat. Moreover, it cannot be assumed that there will be no changes to the roadless rule as it is currently under judicial review. In designated Wilderness and WSAs, mining claims that pre-date the Wilderness Act may be pursued. Livestock grazing is also permitted on these lands.

Response—In response to concerns about our portrayal of the USFS designations of Wilderness areas, WSAs, and IRAs in the proposed rule, revisions were made to the final rule (see *Factors A and D*) that provide clarification to our description of the USFS designations of Wilderness, WSAs, and IRAs, and the protections each of these designations provide. Although it is true that development can occur in conjunction with oil and gas leases that pre-date the roadless rule, these claims must be valid to be pursued and the plans of operation are subject to reasonable regulations to protect roadless characteristics, with mitigation to offset potential impacts from development. Although motorized roads and trails may occur in roadless areas, they are subject to forest travel management plans. The roadless rule is no longer under judicial review and was upheld by the Tenth Circuit Court of Appeals in *Wyoming* v. *United States Department of Agriculture,* 661 F.3d. 1209 (10th Cir. 2011). If valid mining claims are pursued, the plans of operation are subject to reasonable regulations to protect wilderness values with mitigation to offset potential effects from development. Although preexisting livestock permits are allowed under these designations, new livestock allotments are not permitted in these areas.

Issue 95—Some public commenters expressed concern about the USFS plans and how they will be implemented. One commenter expressed that the USFS's 2005 guidelines for habitat outside the PCA are not legally enforceable. One commenter suggested that, once delisting is finalized, the 2006 Amendment cannot simply be reinstated and implemented; the USFS needs to do a new planning and public review process to amend their plans because the new 2016 Conservation Strategy changes the habitat protections that must be provided by existing forest plans and removes the current tools and incentives. Commenters requested additional detail on when these amendments would be made and how the public would be involved in the review. A commenter noted that, after delisting, NF lands must have mechanisms for protecting grizzly bears, providing connectivity between habitats, and ensuring adequate habitat protections; commenters were concerned that these mechanisms were missing or remained in drafts unavailable to the public. Lastly, while some comments expressed that the USFS plans are not regulatory because of the 2012 Planning Rule, others expressed that the 2012 Planning Rule requires the USFS to consider connectivity, including roads (permanent or temporary, open or closed) and site development in light of how they may increase human-bear conflicts and grizzly bear mortality.

Response—In its 2011 decision, the Ninth Circuit Court supported the Service's conclusion that incorporation

of the 2007 Conservation Strategy's habitat standards into legally enforceable national forest land management plans and the NPS' Superintendent's compendia were adequate regulatory mechanisms. The 2006 Forest Plan Amendment was consistent with the habitat guidance in the 2007 Conservation Strategy (USDA FS 2006b, entire). Since 2007, the Beaverhead-Deerlodge, Shoshone, and Gallatin NFs have incorporated the habitat direction in their forest plans amendments or revisions (Beaverhead-Deerlodge NF 2009, p. 47 and Appendix G; Gallatin NF 2015, p. II–4 and Appendix G; Shoshone NF 2015, p. 39). The 2006 Forest Plan Amendment still stands for the Custer, Bridger-Teton, and Caribou-Targhee NFs and will be implemented when delisting is final. The six GYE NFs compared the 2007 and 2016 Conservation Strategies to assess if changes were necessary to the management direction in current forest plans. They ''concluded that current forest plan direction meets the intent of, or is more protective than, the updated 2016 Strategy.''

Whereas minor differences in the application rules and monitoring requirements indicate that the plans will need administrative change, amendment, or revision, these differences do not impact the adequate regulatory mechanisms in current forest plans (Schmid 2017, *in litt.*). Although some of the current forest plans fall under the 1982 Planning Rule, any revisions and amendments would be in compliance with the 2012 Planning Rule. Under the 2012 Planning Rule, forest plan revisions and amendments must use the best available science and are subject to the same public process and litigation as they were previously. In contrast to the 1982 Planning Rule, compliance with both standards and guidelines are required under the 2012 Planning Rule. Projects occurring on Federal lands, such as road development, timber projects, and oil, gas, and mining projects, must undergo NEPA analysis to evaluate impacts on grizzly bears and their habitat whether the grizzly bear is listed or delisted.

Genetic Health Issues (Factor E)

Issue 96—Public commenters raised concerns about the scientific rigor of our analysis of genetic viability. Many commenters suggested that the isolated GYE grizzly bear population has a shrinking gene pool and lacks genetic diversity since: (1) The population resulted from a genetic bottleneck, (2) the population has lacked connection to any other grizzly bears for over a century, and (3) the bears have lost 15 to 20 percent of their genetic variability in the last 100 years (Craighead *et al.* undated). Other commenters warned of the perils to small, isolated, low-genetic-variability populations from inbreeding, genetic abnormalities, birth defects, low reproductive rates, low survival rates, susceptibility to extinction from disease and parasites, and eventual population declines that can result in extinction or speciation. Commenters pointed out that genomic changes are slow and take decades to detect and that declines in the GYE grizzly bear population will further deplete extant levels of genetic diversity.

A few commenters suggested potential additional analysis and modeling to consider in our analysis of genetic viability such as: (1) Models of the rate of allele loss due to genetic drift at various population sizes (though the long-term fitness implications of changes in allelic diversity are not well understood); and (2) projections of the evolutionary health of the GYE grizzly bear population.

Several comments raised concerns over the scientific basis for our lower limit of 500 bears for genetic viability, saying this threshold ensures only short-term genetic fitness and is based on outdated science (Franklin 1980) when more recent critical assessments of this standard are available (Frankham *et al.* 2014; Ewens 1990); States suggested that we incorrectly suggested that 500 bears is required for short-term genetic fitness when Miller and Waits (2003) require only 400. Commenters thought anywhere from 500 bears to 19,800 bears were necessary for long-term genetic viability (Frankham *et al.,* 2013); they suggested that the current actual or effective population size in the GYE is not sufficiently large to ensure long-term genetic viability.

Other commenters took issue with our calculation and analysis of effective population size. A few commenters thought the actual effective population size was lower than the 469 bears we reported and thus not yet at the long-term viable population criterion of more than 500 bears because: (1) ''effective population size is approximately 25–27 percent of total population size,'' suggesting a true effective population size of only 179 bears given recent population estimates (Allendorf *et al.* 1991, p. 650; Miller and Waits 2003; Groom *et al.* 2006, p. 405); and (2) we selectively reported the upper end of the effective population estimate of 469 bears when we should have chosen the more conservative estimates discussed by Kamath *et al.* (2015). One commenter opined that we did not explain how effective population size (N_e) and number of effective breeders (N_b) differ, nor did we offer the benefits and downsides of these different metrics from Kamath *et al.* (2015). This commenter also claimed that we did not use the best available science in calculating N_e and N_b (the SF/SA or Sibling Frequency/Assignment method) and instead used a method scientists have yet to fully review (EPA or Estimator of Parentage Assignments) (Wang 2016; Waples 2016), which overestimates trends in these parameters.

Conversely, one commenter stated that the scope of the discussion of genetics in the proposed rule was too broad and that the Service should instead clearly state that ''current genetic diversity sufficiently supports the delisting decision and that future management of genetic diversity after delisting is a separate matter to be managed as described in the Conservation Strategy.''

Several public commenters raised concerns over connectivity and how genetic connections between grizzly bear populations could become more challenging to facilitate in a post-delisting environment (see Issue 50 for a more detailed discussion of public and peer-reviewer concerns about connectivity). Commenters claimed that lack of connectivity to other grizzly bear populations, habitat fragmentation, and habitat loss present a ''long-term genetic risk for Yellowstone grizzlies'' (Haroldson *et al.* 2010). One commenter felt that reintroductions into other ecosystems were the best option to expand the gene pool, restore gene flow, and increase fitness. Another commenter even suggested periodic transplants from Canada to enhance genetic diversity. One comment stated that we dismissed the need for immigration in our proposed rule and that the 2016 Conservation Strategy and the Tri-State MOA do not commit to providing transplants to ensure genetic quality; commenters suggested that, without binding commitments to connecting the GYE to northern populations, ensuring limited mortality in connective corridors, and transplanting bears, the genetic health and evolutionary capacity of the GYE population would be at risk.

Many commenters weighed in on potential transplant programs. One commenter asked us to provide more justification behind our assertion that one to two immigrants or transplants per generation is an adequate level of gene flow into the GYE (Miller and Waits 2003). Some commenters suggested that managers would need to transplant anywhere from 7 to 15 bears

per decade into the GYE considering the likelihood of survival and reproduction. One commenter worried that a translocation program would be labor intensive and could jeopardize the health of the source population, especially if managers aim to move mostly females into the GYE. A few commenters stated that management should place more effort on facilitating natural dispersal instead of relying on translocations. The States requested removal of any language suggesting migrants will be necessary for genetic health of the GYE population and that the final rule more explicitly state that ''genetic connectivity is not required for delisting, and that the genetic health of the GYE DPS is very strong.''

Response—Our analysis of genetic viability is based on peer-reviewed literature that specifically addresses genetics of the GYE grizzly bears, as well as other relevant genetic literature. Kamath *et al.* (2015, entire), combined with Miller and Waits (2003, entire), suggests that although the GYE grizzly bear population is isolated there is no evidence of a ''shrinking gene pool.'' Although the current effective population size for the GYE grizzly bear is lower than what is recommended by published literature on evolutionary theory (*e.g.,* Franklin 1980, p. 136) for evolutionary success in the absence of management, it is important to note that the recommendation is based on non-managed populations. We remain confident that genetic management for the GYE grizzly bear population will effectively address future genetic concerns (Hedrick 1995, p. 1004; Miller and Waits, p. 4338).

Because it is generally accepted that isolated populations are at greater risk of extinction over the long term, the 2016 Conservation Strategy (YES 2016a, pp. 82–84) identifies and commits to a protocol to encourage natural habitat connectivity between the GYE and other grizzly bear ecosystems. Although natural connectivity is the best possible scenario, isolation does not constitute a threat to the GYE grizzly bear in the foreseeable future because of intensive monitoring and adaptive management strategies that will remain in effect post-delisting. Based on the best available science (Miller and Waits 2003, p. 4338), the Service concludes that the genetic diversity of the GYE grizzly bear population will be adequately maintained by the immigration or relocation of one to two effective migrants from the NCDE every 10 years. Effective migrant is defined as a bear from another ecosystem that breeds with GYE bears and successfully reproduces. Thus, immigration of more than 1 or 2 bears may be needed, depending on survival and reproductive success of the migrants. See YES (2016a, pp. 51–53) and discussion under *Factor E* in this final rule for more information. This movement of grizzly bears between ecosystems may occur naturally or through management intervention. If management intervention is used, such translocations are not expected to have any discernible impact on the source population because of the relatively small number of bears needed and the timeframe of 10 years—and particularly because the most likely source population (NCDE) is healthy and large in size. Regardless of the method, the Service is confident that genetic impoverishment will not threaten the GYE grizzly bear population.

Connectivity between the GYE and the NCDE is a long-term goal for the State of Montana, as set out in their Grizzly Bear Management Plan for Southwestern Montana (MFWP 2013, pp. 41–44). This connectivity would provide the desired gene flow for long-term genetic fitness of the GYE population. Frankham *et al.* (2014, entire) reviewed the 50/500 rule of Franklin (1980, entire) and proposed an upward revision to at least 100/1000, to which Franklin *et al.* (2014, entire) published a rebuttal stating that, although a larger effective population size is preferable, Frankham *et al.* (2014, entire) ignored the fact that natural selection operates on phenotypes and the 50/500 is still appropriate guidance. Ewens' (1990, entire) concerns with Franklin's (1980, entire) 50/500 rule arise from their misinterpretation that 500 is a minimum population size derived from an N_e of 50 when the 50/500 rule is the N_e for short-term and long-term genetic fitness, respectively.

Our analysis of N_e using 469 bears reflects one method (EPA or Estimator of Parentage Assignment) reported by Kamath *et al.* (2015, p. 5512), which shows a 4-fold increase when compared to the same method applied to historical data of 102 in 1982. Other methods used both by Kamath *et al.* (2015, pp. 5512–5514) and historically by Miller and Waits (2003, p. 4337) did result in lower estimates of N_e, but with a consistent trend of all methods showing a significant increase in the N_e from historical data to 2007. Wildlife genetics is a rapidly evolving and technical field, where the use of newly developed techniques and approaches is commonplace. Wang (2016, entire), for example, compared the accuracies of different single-sample estimators of N_e, but those analyses did not directly compare estimates with those in Kamath *et al.* (2015), nor did the author suggest that EPA-based estimates are not reliable or somehow inferior to other techniques. Kamath *et al.* (2015, entire) based their inference on multiple techniques for estimating effective population size, and explicitly discussed their benefits and caveats. Regardless, although the EPA technique to estimate N_e is relatively new, it has been reliably applied to numerous species, including other brown bear populations.

Although the current N_e of 469 (Kamath *et al.* 2015, p. 5512) is approaching, but has not reached, the long-term viable population criterion of an N_e 500 bears (Franklin 1980), we are confident that the, as yet, lack of N_e does not currently pose a risk to the GYE grizzly bear population's viability. The N_e has increased nearly 4-fold since 1982, combined with a lack of evidence of loss of genetic diversity (only 0.2 percent rate of inbreeding) during 1985 to 2010, and more than a 3-fold increase in N_e (variance effective or N_{ev}) since the early 1900s, based on both Kamath *et al.* (2015, entire) and genetic factors.

The high ratio of effective population size to census population size (N_e/N_c) of 0.66 reported by Kamath *et al.* (2015, p. 5513) most likely reflects the underestimation bias of the Chao2 estimator (see Issues 16 and 28). These ratios were lower when using the Mark-Resight estimate ($N_e/N_c = 0.42$), suggesting that the Mark-Resight estimate is much closer to the true population size than the Chao2 estimate (Kamath *et al.* 2015, p. 5517). However, Mark-Resight is not the best available science because investigations into Mark-Resight discovered that it was unable to accurately detect population trend. In addition, reported ratios of N_e/N_c have varied widely across grizzly bear populations (0.04–0.6; Paetkau *et al.* 1998, p. 424; Miller and Waits 2003, p. 4337; Schregel *et al.* 2012, p. 3482), with the ratios of 0.42–0.66 falling towards the upper middle of that range. Recovery criterion #1 identifies 500 individuals as a minimum population to ensure short-term genetic fitness and is not a population goal. Five hundred bears provides a buffer above the total population of 400 (N_e of 100) recommended by Miller and Waits (2003, p. 4338) for short-term genetic health.

Indicators of fitness in the GYE population demonstrate that the current levels of genetic heterozygosity are adequate, as evidenced by measures such as litter size, little evidence of disease, high survivorship, an equal sex ratio, normal body size and physical characteristics, and a stable to increasing population. None of these

indicators provide any evidence that inbreeding has affected fitness, and research on other species (*e.g.,* Florida panther) indicates such effects typically manifest themselves only at extremely small population sizes. These indicators of fitness will be monitored annually, in perpetuity. The very low rate of loss of heterozygosity over the 20th century, in combination with the introduction of 1 or 2 effective migrants per generation (naturally or through augmentation), will ensure long-term genetic viability, and the recovered status, of the GYE grizzly bear DPS (Miller and Waits 2003, p. 4338). Although Miller and Waits (2003, p. 4338) measured a decline in allelic richness from the 1910s to the 1990s it had not declined as precipitously as previously anticipated, and Kamath *et al.* (2015, p. 5512) showed no statistical support for a decline in mean allelic richness from 1985 to 2010. Based on all of the information available that examines heterozygosity and allelic diversity in the GYE grizzly bear population, researchers concluded that genetic factors are unlikely to compromise the viability of the population in the near future (Miller and Waits 2003, p. 4338; Kamath *et al.* 2015, p. 5517). The IGBST will continue to monitor genetic diversity in the GYE grizzly bear population as set forth in the 2016 Conservation Strategy (YES 2016a, pp. 51–53). Although genetic connectivity is not necessary for the current genetic health of the GYE grizzly bear population, it is desired.

Food Resources Issues (Factor E)

Issue 97—Public commenters challenged the validity of our analysis of the effects of food availability on grizzly bear health, citing potential flaws in our conclusion that female grizzly bears have sufficient body fat including: (1) A study by Schwartz *et al.* (2013), which shows a recent decline in body fat among female grizzly bears; (2) suggestions that the study we referenced ''included bears that were not captured specifically for monitoring change in body fat levels'' and only ''included female grizzly bear fat level data from spring and summer;'' and (3) notes that even if females have adequate levels of body fat in the spring and summer, they could still be fat deficient in the fall.

Other commenters worried about the defensibility of the IGBST's models analyzing the effects of food availability on grizzly bear populations; these commenters noted that much of the IGBST's data for these models comes from observational studies, which makes it difficult to isolate the effects of individual variables or rule out other confounding drivers of birth and death rates, such as spatial and temporal correlations. Finally, one commenter claimed that the three IGBST papers (Bjornlie *et al.* 2014b, Costello *et al.* 2014, and van Manen *et al.* 2015) did not account for long-term weather trends or changes in the abundance of key foods (*i.e.,* army cutworm moths, cutthroat trout, and ungulates) other than whitebark pine in their analysis of vital rates.

Response—In their papers and reports, the IGBST recognized a potential decline in the trend of percent body fat among females after 2006, as presented in Schwartz *et al.* (2014a, p. 73). However, the IGBST also clarified that those findings provided weak inference because they were based on very small annual sample sizes and that additional investigations were needed. For example, extending the female body fat figure from Schwartz *et al.* (2014a, p. 73) by several more years (see figure 4; IGBST, unpublished data), provides a stable instead of decreasing trend, which is why interpretation of sparse data should be done cautiously. This is also why the IGBST in the Food Synthesis report (IGBST 2013, pp. 18–20) presented an alternative analysis of body fat data, with appropriate caveats, that did not support the hypothesis that the rate of body fat gain over the active season was different for the period before versus after the period of peak whitebark pine decline.

We contend that a key point regarding female body condition, changes in food resources, and reproduction has been overlooked: Female grizzly bears without adequate nutrition to support reproduction, especially in YNP where bear densities are high and from where the fall sample of female percent body fat is taken, would not support the trend in counts of females with cubs-of-the-year within YNP, or the entire ecosystem (see YES 2016a, figures 3 and 4). For example, the highest counts of females with cubs-of-the-year were in 2013 and 2014, approximately 6 to 7 years after the peak of whitebark decline and more than a decade after the start of decline. Additionally, compared with the body fat data, the inference based on vital rates (*i.e.,* survival of different sex and age classes, fecundity) is much stronger and does not support the hypothesis that food resources have affected reproductive rates. Only a moderate decline in fecundity has been observed, and the IGBST documented those declines were greater in areas with higher grizzly bear densities and were not associated with decline of whitebark pine tree cover (van Manen *et al.* 2016, p. 308).

The vital rates that showed the greatest change, and caused the slowing of population growth since the early 2000s, are lower cub and yearling survival (*i.e.,* lower recruitment into the population). The IGBST investigated if the decline in cub and yearling survival could be a function of decline in food resources (whitebark pine) or whether associated with grizzly bear density. Survival of cubs-of-the-year was lower in areas with higher grizzly bear densities but showed no association with estimates of decline in whitebark pine tree cover, suggesting that grizzly bear density contributed to the slowing of population growth (van Manen *et al.* 2016, p. 308). Other studies support the interpretation of density effects playing an increasingly important role in the ecology of GYE's grizzly bears (Schwartz *et al.* 2006b, p. 1; Bjornlie *et al.* 2014b, p. 5).

There were no compelling reasons to investigate the *direct* relationship of long-term weather patterns on habitat selection, home-range sizes, or demographics of grizzly bears; no literature exists that suggests such relationships exist. Of course, changes in climate may affect the distribution and availability of key foods, such as army cutworm moths, cutthroat trout, and ungulates, but those relationships have not been sufficiently studied to incorporate those into the analyses. Furthermore, with the exception of cutthroat trout, which can be measured but is a local food resource, no reliable metrics exist to measure the distribution and availability of army cutworm moths or ungulates, let alone the ability to measure their temporal and spatial variation. The focus of the analyses in these 3 papers (in their entirety: Bjornlie *et al.* 2014b, Costello *et al.* 2014, and van Manen *et al.* 2016) was on whitebark pine because of (1) the documented relationships between some grizzly bear vital rates and whitebark pine cone production; (2) the existence of long-term, annual monitoring data of whitebark pine cone production, and the ability to estimate decline in canopy cover of mapped whitebark pine; and (3) the emphasis on whitebark pine in the litigation associated with the 2007 delisting rule (72 FR 14866, March 29, 2007).

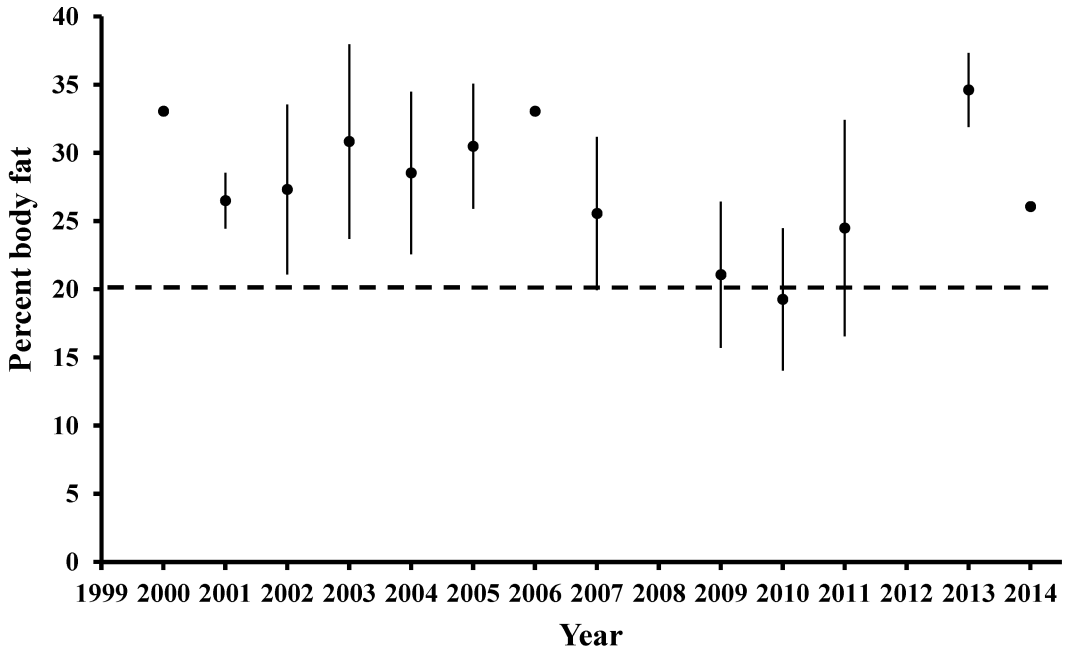

Figure 4. Trend in fall (September–October) percent body fat (mean ± 1 SD) for independent-aged female grizzly bears captured at research capture sites in the Greater Yellowstone Ecosystem, 2000–2015. No fall body fat data for independent females were collected in 2008, 2012, and 2015. Dashed horizontal line represents threshold for reproduction based on Robbins *et al*. (2012, p. 543).

Issue 98—Both public commenters and peer-reviewers suggested additional monitoring and analysis of the availability of food sources and the potential impacts to grizzly bear health. Commenters suggested: (1) An analysis of the movements and home-ranges of females with cubs because, if the home ranges are decreasing, it could bolster claims that the population is approaching biological carrying capacity; (2) discussion of the different hazard levels associated with acquiring different types of high-quality food and whether these hazards are primarily relevant to dependent young, independent bears, or both; and (3) measurement of habitat in terms of food value, with annual and seasonal variations noted. A few commenters worried that the 2016 Conservation Strategy stated that the IGBST would monitor the four main food sources only ''as budgets allow;'' this commenter wondered why the IGBST, and not any other entity, had this ''escape clause'' and how the Service could justify allowing this caveat on food source monitoring since lack of sufficient monitoring of food sources should trigger a status review. Peer-reviewers suggested a regular review of the whole grizzly bear diet in the GYE. And both peer-reviewers and public commenters suggested continued monitoring of the relationship between the availability of the four main food sources, grizzly bear use of the four main food sources, vital rates for the GYE population, and body condition of grizzly bears.

Response—The amount and availability of the four high-caloric foods for grizzly bears will likely fluctuate due to possible changes in average temperature, precipitation, forest fires, introduced species, and resident insects. Changes in environmental conditions and resulting changes in foods for grizzly bears have been recognized by management agencies throughout the recovery process (see *Factor E: Catastrophic Events* in the rule for further discussion). That such changes will occur is neither exceptional nor unexpected. The key issue is determining if and how bears are adapting to such changes and how management agencies can facilitate adaptation. The compounded uncertainties associated with projections of possible future habitat changes, predicted responses of grizzly bears to multiple possible future conditions, and assumed changes to vital rates in response to any such possible future habitat changes create a wide realm of possible responses.

Rather than use such a compounded uncertainty approach, the management system outlined in the 2016 Conservation Strategy (YES 2016a, pp. 33–85) depends on monitoring of multiple indices including production and availability of the four high-caloric foods; and monitoring of grizzly bear vital rates including survival, age at first reproduction, reproductive rate, cub survival, mortality cause and location, dispersal, and human-bear conflicts. The IGBST will annually report to the YGCC on the monitoring results of food production, bear mortality, and females with cubs-of-the-year. In addition, the IGBST will conduct a demographic monitoring review of the population vital rates every 5 to 10 years. The relationships between these factors will detect any impacts of changes in foods on bear viability in the ecosystem and will be the basis for an adaptive management response by the YGCC to address poor food years with responsive actions such as limiting grizzly bear mortality, increasing I&E efforts, and long-term habitat restoration (*e.g.,* revegetation, prescribed burning), as appropriate. The continued monitoring of these multiple indices will allow rapid feedback on the success of management actions to address the

objective of maintaining a recovered population.

Future studies will be directed to address further questions regarding grizzly bear responses to changing food resources and changing environmental conditions. Female home ranges decreased in size from the period of 1989 to 1999 and 2007 to 2012 with the decrease being greater in areas with higher grizzly bear densities, supporting evidence that the population is reaching carrying capacity (Bjornlie *et al.* 2014b, pp. 4–6).

It is impossible to calculate with any degree of certainty the extent to which natural foods will change across the landscape and any resulting effects on bears. With the exception of whitebark pine, there are no documented relationships among grizzly bear demographic rates and the consumption of other grizzly bear foods, such as cutthroat trout, army cutworm moths, or ungulates. It is important to note that the annual abundance and distribution of whitebark pine seeds, as well as other food sources, vary naturally, annually and spatially, and are not predictable. Thus, it is not biologically possible to define ''baseline'' levels for various foods, and the monitoring system discussed above is a more robust approach. During years with little or no whitebark pine seed production, grizzly bears switch to alternative foods. Indeed, the effect of whitebark pine crops on survival of independent-aged grizzly bears is relatively minor: For example, based on Haroldson *et al.* (2006, p. 39), annual survival among female bears that were not involved with conflicts varied very little and was 94.7 percent, 95.7 percent, and 96.5 percent after years with median whitebark pine counts of 0 (*i.e.,* no crop), 7.5 (average crop), and 15 (high crop), respectively.

The caveat of food source monitoring ''as budgets allow'' has been removed from the 2016 Conservation Strategy. Please see Issue 85 for further discussion on funding being a trigger for a status review.

Issue 99—Several public commenters asserted that we inaccurately downplayed the importance of the four main food sources. Commenters suggested that the four main food sources are still uniquely important because: (1) The IGBST continues to monitor only these four food sources; (2) fat is especially important and is uniquely abundant in army cutworm moths, whitebark pine seeds, and late-season ungulates (Mattson *et al.* 2004; Erlenbach *et al.* 2014); (3) historically, grizzly bears have relied on the four main food sources and only fed on other foods opportunistically; (4) the list of more than 200 grizzly bear foods cited in Gunther *et al.* (2014) is inflated because to a bear ''a grass is a grass;'' (5) the use of false truffles during poor whitebark pine years was only documented in the core of the ecosystem and there was also no indication of the nutritional value of this food source; and (6) bear densities vary widely depending on habitat productivity (Mowat *et al.* 2013), which commenters suggested ran counter to our claims that grizzly bears are extremely flexible in their diet and thus resilient to changes in food abundance.

Commenters noted that the nutritional value (*i.e.,* fat, protein, and gross energy), seasonal abundance, and risk and energetic cost of obtaining any alternative food source must be comparable to the four main food sources. One commenter expressed concern that the Food Synthesis Report does the minimum to satisfy the requirement of the Ninth Circuit ruling; the commenter argued that researchers should have done a robust assessment of the four key food sources, at the very least, to detect diet changes.

Response—Aside from the well-documented association between whitebark pine cone crop size and subsequent management actions on grizzly bears (Mattson *et al.* 1992, p. 432), we have not been able to detect any cause-effect relationships between abundances of the three other major foods and grizzly bear vital rates. Those foods have either fluctuated (*e.g.,* ungulates, army cutworm moths) or declined (*e.g.,* cutthroat trout) during the period in which the GYE grizzly bear population was stable to increasing.

While we agree that the extent to which grizzly bears might be able to compensate for the loss of one of the four major foods is unknown, the final rule discusses and relies upon the best scientific and commercial data available. Future food source availability and the possible grizzly bear reaction to those possible future changes are discussed under *Factor E,* above, and in Issue 98. We also agree that human-caused mortality is probably the major factor limiting grizzly bear populations, although mortality can be mediated by food availability (Mattson *et al.* 1992, p. 432). The IGBST will continue to monitor major food abundance and grizzly bear conflicts and mortalities. The combination of results and IGBST analyses from these multiple monitoring indices on foods, bear vital rates, and bear-human conflicts will allow managers to respond to changes as necessary (see Issue 98).

The use of the four high-caloric foods should not be interpreted that these foods are essential for a sustainable grizzly bear population in the GYE. In the 2013 Food Synthesis Report, the IGBST suggested a paradigm shift may be needed in reference to the importance of whitebark pine to grizzly bears (see IGBST 2013). When comparing one food item to another, it is unrealistic to expect that any alternative food is fully comparable in the factors mentioned above (*e.g.,* risk, nutritional value). Even when the full suite of alternative foods is considered, this would be an unrealistic expectation. Ultimately, what matters is that use of alternative food resources does not substantially affect bears at either the individual level (*e.g.,* body condition, home-range size) or the population level (*e.g.,* does not affect vital rates or mortality patterns). These issues were thoroughly addressed in the Food Synthesis Report and associated peer-reviewed publications (in their entirety: IGBST 2013; Bjornlie *et al.* 2014b; Costello *et al.* 2014; Gunther *et al.* 2014; Schwartz *et al.* 2014a, 2014b; van Manen *et al.* 2016; Ebinger *et al.* 2016; Haroldson *et al.,* in prep.). The IGBST conducted extensive analyses as part of the Food Synthesis Report and addressed multiple research hypotheses to increase confidence in their ability to draw inferences from the data; this analysis resulted in seven peer-reviewed journal articles, several associated reports, and a number of popular science articles. Therefore the suggestion that this comprehensive research effort ''does the minimum to satisfy the requirement of the Ninth Circuit ruling'' is not factual.

Although we agree that, in general, to a bear ''a grass is a grass,'' grizzly bears feed on multiple species in each phylogenetic kingdom including: 162 plant species (4 aquatics, 4 ferns and fern allies, 85 forbs, 31 graminoids, 31 shrubs, and 7 trees); 7 fungi species; 70 animal species (1 amphibian, 3 birds, 4 fish, 26 mammals, 33 insects, 1 mollusk, 1 segmented worm, and 1 spider); and 1 protista (algae). Within the plant kingdom, energy content may be as high as 2.52 kilocalories/gram (kcal/g) for grasses and sedges to 4.83 kcal/g for clover (whitebark pine seeds are 3.24 kcal/g); protein content may be as high as 21.1 percent for bear grass to 39 percent for the pre-flowering foliage of spring beauty; fat content may be as high as 15.6 percent for bear grass to 30.5 percent for whitebark pine seeds; and carbohydrate content averaged 55 percent for berry species and was as high as 88.8 percent for onion grass

bulbs (Gunther *et al.* 2014, pp. 63–64). Macronutrients vary widely between plant species and within plant species as they mature, with new growth having the highest protein content, and between plant parts (Robbins 1993, entire). Grizzly bears are a generalist omnivore, which allows them to optimize their fitness by adjusting their energy and macronutrient intake (*i.e.,* protein, fat, and carbohydrates) (Erlenbach *et al.* 2014, pp. 163–164). Research by Fortin *et al.* (2013a, p. 277) that found females using false truffles in the absence of whitebark pine were focused around the Yellowstone Lake area; however, Gunther *et al.'*s (2014, entire) study shows the magnitude of diet fluctuation of grizzly bears throughout the GYE, and the Food Synthesis Report (IGBST 2013, entire) does not show any substantial effects to grizzly bears at the individual or population level as a result of switching from declining whitebark pine resources to using alternative food sources. Additionally, false truffles averaged 4.8 kcal/g and 11.3 percent crude protein (Fortin data, unpublished), which is close to the highest energy found for plants as discussed in Gunther *et al.* (2014, p. 63).

We do not dispute that bear densities vary widely between ecosystems depending on habitat productivity, as it is one factor that may change carrying capacity in an ecosystem; however, the ability of grizzly bears to survive in such a variety of habitat types with large differences in available food sources (*i.e.,* coastal salmon-eating bears to interior bears that are largely herbivorous) is a testament to their dietary flexibility. In addition, there is no evidence that carrying capacity has declined in the GYE (van Manen *et al.* 2016, p. 309). Ongoing demographic monitoring by the IGBST would be able to detect such a decline and be reported to the YGCC for appropriate adaptive management, should it be deemed necessary, to maintain a recovered grizzly bear population in the GYE.

Issue 100—We received several comments from the public regarding current and future effects of reported declines in food resources, including: (1) Increased home range size and dispersal distance as an effort to find food, which could lead to increased bear mortalities; (2) changes in birth and death rates; (3) past declines in the population growth rate from the 4 to 7 percent annual increases to 0.3 to 2.2 percent annual increases; and (4) leaner female bears that will not produce as many cubs. A peer-reviewer suggested that declines in food sources could have corresponding declines in a habitat's carrying capacity for grizzly bears.

Peer-reviewers and commenters also provided input on potential management of declining food sources. A peer-reviewer disagreed with our statement that ''land managers have little influence on how calories are spread across the landscape'' and suggested a few examples of management actions that affect food distribution, including: ''increasing ungulate densities through improving habitat and controlling hunting harvest; improving fish stocks and habitat; controlling invasive species to protect native food resources desired by grizzly bears;'' and increasing bison populations by limiting lethal control of bison as a means of managing brucellosis. One commenter suggested that the grizzly bear should not be delisted because its food sources are declining and it has restricted access to additional food sources outside a protected range.

Response—The comments we received about the potential effects of declines in food sources are addressed by summarizing several key findings of the Food Synthesis Report (IGBST 2013, entire) and associated peer-reviewed publications (see Issue 37 and *Factor E* for more details). The overall findings of the Synthesis Report provided evidence that grizzly bear responses to changing food resources were primarily behavioral, with bears demonstrating substantial capacity to adjust their diets to include alternative foods. If overall food resources were declining, we would expect daily movements, fall movements, and home-range sizes to increase if bears were roaming more widely in search of foods, as suggested by commenters. However, movement rates did not change during 2002 to 2011, suggesting that grizzly bears were finding alternative foods within their home ranges (Costello *et al.* 2014, p. 2013). For females, home ranges actually decreased in size from the period before (1989 to 1999) to after (2007 to 2012) whitebark pine decline, whereas male home ranges did not change in size (Bjornlie *et al.* 2014b). This decrease in female home range size was greater in areas with higher grizzly bear densities but showed no relationship with amount of live whitebark pine in the home range (Bjornlie *et al.* 2014b, pp. 4–6). Finally, at the population level, bear density, but not whitebark pine decline, was associated with lower cub survival and slightly lower fecundity, factors directly contributing to the slowing of population growth since the early 2000s. The combined findings of these studies suggest that carrying capacity for grizzly bears in the GYE is not so much a function of available food resources but more a function of high bear density in portions of the ecosystem. Body fat data for females in the GYE collected beyond those presented by Schwartz *et al.* (2014a, pp. 72–73) (*i.e.,* since 2011) were well above the 20 percent threshold for reproduction published by Robbins *et al.* (2012, p. 543).

Several of the suggestions for management of declining food sources are already being implemented (*e.g.,* cutthroat trout restoration in Yellowstone Lake, invasive species control) by land managers. Additionally, some food resources that grizzly bears consume are not native (at least 13 species; Gunther *et al.* 2014, p. 63) and may even be considered invasive. Finally, several of these suggestions may not be feasible for managers to implement as they would require managers to disregard other priorities. For example, bison populations actually have to be culled occasionally to prevent ecological damage due to overpopulation; therefore, increasing the bison population size is not a viable option. The IGBST will continue demographic monitoring of the GYE grizzly bear population and will present their findings to the YGCC, who could then decide if modifications to the 2016 Conservation Strategy were necessary.

Issue 101—Commenters asserted that grizzly bears have grown to depend on army cutworm moths and benefit from their consumption; specifically, (1) grizzly bears had almost no consumption of the moths in the 1980s but had high sustained use in the 1990s; and (2) moths are a high-fat-content food source (leading to greater fecundity) and that the remoteness of most moth sites has led to a reduction in human-caused mortality. As such, one commenter suggested that use of army cutworm moths must be encouraged. However, another commenter noted that there is a high correlation between moth habitat and grazing allotment location, thus potentially increasing the risk of human-caused mortality.

Commenters maintained that we did not account for the effect of increasing moth use on birth and death rates and, without this analysis, we cannot determine ''future effects of losses of this food on the population.'' Commenters suggested reasons to worry about recent declines in and the future abundance of moths, and the associated health of grizzly bears, including: (1) Concerns about the unknown responses of moths if up to 90 percent of the subalpine and alpine habitat upon

which they depend is lost by 2099, as is predicted in some climate change models; (2) concerns about the potential impacts of pesticide use and new farming technologies; and (3) suggestions that the USFS needs to address the issue of human activity at moth aggregation sites and the potential disturbance to grizzly bears feeding at those sites. One commenter stated that all of the 31 known army cutworm moth sites are located on USFS lands (Gunther 2014); 6 of those sites are located outside of the PCA. Though commenters worried about potential future declines in moths, a peer-reviewer noted that ''bear use of army cutworm moth sites may not be a good measure of cutworm moth relative abundance because grizzly bears may return to areas where they've found abundant food sources in the past even though those resources are not present.''

Response—The final rule contains a discussion of the potential effects of both global climate change and pesticides on army cutworm moths. There is no evidence to suggest that spraying of army cutworm moths has any population-level effects on grizzly bears (Robison *et al.* 2006b, pp. 1706–1710). The Shoshone NF is cooperating with other agencies to gain knowledge about the ecology of army cutworm moths, grizzly bear use of moth sites, and grizzly bear-human interactions at moth sites (Shoshone NF 2015, p. 45). New permitted activities at moth sites are restricted until a comprehensive site-management plan is developed (Shoshone NF 2015, p. 41). It is highly unlikely that any of the high-elevation sites used by the moths, all of which are on public lands, will be exposed to development.

There is no accurate method available to monitor moth numbers across thousands of square kilometers of alpine habitat. The current, best available method quantifies bear use of moth sites as an index of moth presence and distribution. Although it is known that moth abundance fluctuates in the spring on agricultural lands on the plains (Burton *et al.* 1980, pp. 4–5) and that moth flights vary in magnitude along their migration routes (Hendricks 1998, p. 165), we are not able to predict where army cutworm moths will occur on the landscape each year except by observing where bears use this food source. The IGBST is currently sponsoring the development of spatial models to predict locations of potential army cutworm moth habitat (Robison *et al.* 2006a, p. 88). The IGBST has not documented an association between grizzly bear use of moth aggregation sites and variation in vital rates, including survival, and, therefore, the direct monitoring of army cutworm moth abundance and status is not necessary at this time.

Issue 102—Commenters had concerns about the status of cutthroat trout. Citing Haroldson *et al.* (2005), one commenter challenged our assertion that only a small portion of GYE bears use cutthroat trout and claimed that 15 percent or more of GYE grizzly bears eat this food source: Another commenter suggested increasing usage should be encouraged. One commenter questioned the disparity between males and females in their use of cutthroat trout that Mattson and Reinhardt (1995) discuss in contrast to Haroldson *et al.* (2005) and Felicetti *et al.* (2004).

Several comments stated that there has been a substantial decrease (almost 90 percent) in the cutthroat population due to predation by nonnative lake trout, declines in winter snowfall, total lack of spawning in all tributaries of Yellowstone Lake, increased drought, and subsequent reductions of in-stream flows; commenters suggested that these negative population trends are likely to continue, especially as warmer temperatures could increase incidence of whirling disease. One commenter recommended that more information be provided regarding future populations of trout including impacts to cutthroat trout from lake trout, future management of lake trout, future vulnerability of cutthroat trout to pathogens, and future impacts from climate change.

Commenters suggested that cutthroat trout declines have affected, and will continue to affect, GYE grizzly bears because: (1) The loss of cutthroat trout has left a seasonal gap in the diet of grizzly bears, which bears have filled by consuming elk calves and lower quality vegetation (Fortin *et al.* 2013a, Middleton *et al.* 2013, Ebinger *et al.* 2016), which has likely led to decreases in cub and yearling survival; and (2) a decline in cutthroat trout has decreased carrying capacity in the core of YNP.

Response—Prior to the 1990s, spawning cutthroat trout provided a seasonal food resource for a segment of GYE grizzly bears residing adjacent to the Yellowstone Lake basin. Since highs in the 1970s and 1980s, the cutthroat trout population has decreased to less than 10 percent of historical numbers due to predation by non-native lake trout (*Salvelinus namaycush*), whirling disease (*Myxoblus cerebralis*), and drought (Koel *et al.* 2005p. 16). By as early as 1997, estimates of annual consumption of fish by bears had decreased by 89 percent, with female consumption estimated at exceedingly low levels (8 fish per bear; Felicetti *et al.* 2004, p. 499). However, the GYE grizzly bear population continued to grow through the 1990s and did not slow until the early 2000s, with a shift to stable population rate attributed to the increasing density of grizzly bears within the GYE core (IGBST 2013, p. 31). The fact that cutthroat trout consumption has not directly influenced population-wide growth rates may be due to (1) limited, regional use of cutthroat trout by only a segment of the population, and (2) the demonstrated ability of female bears to perhaps augment losses from cutthroat trout with other available high-quality food items (Fortin *et al.* 2013a, p. 277; IGBST 2013, pp. 21–22; Ebinger *et al.* 2016, p. 704).

As stated previously, trout consumption by female grizzly bears was quite low in the late nineties and continued at similarly low levels into the late 2000s (Felicetti *et al.* 2004, p. 496; Fortin *et al.* 2013a, p. 276). Earlier studies contend that female use of cutthroat trout was higher than that of males in the late 1980s (Reinhart and Mattson 1990, p. 347; Mattson and Reinhart 1995, p. 2075). Discrepancies in results regarding male versus female grizzly bear use of trout may be due to either true shifts in bear behavior, or methods used within studies. Earlier studies relied on telemetry, track sizes, and proximity to streams to estimate consumption of fish by males and females and also assumed equality of trout intake based upon time spent near streams (Reinhart and Mattson 1990, pp. 344–345; Mattson and Reinhart 1995, pp. 2073–2074). Later studies used DNA and mercury analysis techniques to more precisely establish sex of individual bears and estimate fish consumption (Haroldson *et al.* 2005, pp. 170–172; Felicetti *et al.* 2004, pp. 494–496; Fortin *et al.* 2013a, pp. 274–275; Teisberg *et al.* 2014a, pp. 370–372). Because of these differences, no directly comparable estimates exist of female use of trout before 1997.

The Service encourages ongoing efforts to control the lake trout population in Yellowstone Lake. Recent streamside counts indicate that numbers of spawning cutthroat trout are increasing on some tributary streams (Gunther *et al.* 2016, p. 44). Yet, numbers are still at levels far lower than those expected to provide any meaningful resource to grizzly bears in the vicinity of Yellowstone Lake. See Issue 99 for details regarding correlation of grizzly bear populations and food resources.

Issue 103—Many public commenters weighed in on whether whitebark pines,

a grizzly bear food source, are declining. Some commenters believed whitebark pines are not currently declining or are not at risk of future decline because whitebark pines will eventually regenerate, ameliorating the losses that have occurred, and because cone production on remaining whitebark pine trees has doubled, although perhaps only temporarily in recent years, potentially as a result of warmer temperatures. Other commenters provided evidence that whitebark pines are in decline (from blister rust and pine beetle infestations) and that this negative population trend will continue into the future, including: (1) Notes that no whitebark pine cones were produced in the past year on the northern, northwestern, and western perimeters of YNP; (2) suggestions that if we found whitebark pine warranted but precluded for listing under the Act, we should not conclude that whitebark pine decline is not a concern for grizzly bears; (3) research that all whitebark pine in the GYE will be vulnerable to mountain pine beetle by 2070 (Buotte *et al.,* in press); (4) references to climate change models that predict the terminal loss of whitebark pine from the Yellowstone ecoregion; (5) concerns over potential future decline in whitebark pine due to disease, insects, fire, reproductive failure, climate change, and competition from lower elevation species; (6) suggestions that whitebark pine cannot adapt rapidly enough to changing environmental conditions given its long generation length; (7) claims that any newly planted resistant whitebark pine will take 80 years to produce seeds for grizzly bears to eat (which will be too late to help grizzly bears); and (8) suggestions that 75 percent of whitebark pine forests have already disappeared.

Commenters also disagreed on whether potential whitebark pine declines would negatively affect grizzly bear populations. Most peer-reviewers and some commenters did not believe these declines represented a threat to the GYE population because: (1) The IGBST provided a report in 2013 (which YES accepted) showing that declines in the availability of whitebark pine seeds would not lead to declines in grizzly bear populations; (2) the population has increased since 2001, concurrent with whitebark pine population decline; and (3) whitebark pine is not present within the home ranges of approximately one-third of all GYE grizzly bears and thus should be considered an opportunistic food source rather than a fall staple. However, another commenter questioned whether this absence of whitebark pine was natural, or a result of beetles and blister rust). Conversely, other commenters suggested that the decline in whitebark pine is a more serious stressor on the GYE grizzly bear population than we acknowledged in our proposed rule because: (1) Whitebark pine is the most important food source for GYE grizzly bear; (2) we overlooked how whitebark pine die-offs and grizzly bear vital rates declined simultaneously; (3) despite current positive grizzly bear population growth rates, the threat of declining whitebark pine could still be substantial and the grizzly bear population may be unhealthy; (4) contrary to our analysis in the proposed rule, the GYE population of grizzly bears may not adapt to losses of whitebark pine simply because the NCDE population of grizzly bears has continued to grow in the absence of whitebark pine; (5) low whitebark pine production results in grizzly bears seeking food sources associated with humans, leading to increased conflict between bears and humans; (6) ''Nearly 20% of females handled during 2008–2013 had season-specific body fat levels low enough to put them at risk for reproductive failure, whereas prior to 2004, no females assessed were so clearly deficient in body fat;'' and (7) the most severe losses in whitebark pine have occurred too recently to detect long-term population impacts, especially considering grizzly bear's slow reproductive rate.

A few commenters expressed concerns over the methods of our analysis, including: (1) Concern that our analysis of whitebark pine availability did not account for the loss of whitebark pine that occurred in a 1988 fire and the subsequent lack of regeneration; (2) a request that we provide additional detail on the protocol we use to monitor the location and availability of whitebark pine, suggesting that our protocol may be inadequate or outdated; (3) concern that the three IGBST papers analyzing whitebark pine (Bjornlie *et al.* 2014b; Costello *et al.* 2014; and van Manen *et al.* 2015) failed to account for long-term trends in weather and for major changes in abundance of other key food sources (army cutworm moths, cutthroat trout, elk, and bison); (4) concern that the method that the IGBST uses to measure whitebark pine abundance (remote sensing) underestimates the extent of whitebark pine loss and the historical use of whitebark pine by grizzly bears; and (5) warnings against Type II error (*i.e.,* even though there was not a statistical correlation between the decline in whitebark pine and body fat does not mean the relationship does not exist) and how the use of pooled data and small sample size can contribute to Type II errors.

A number of commenters suggested we consider additional analyses, such as: (1) The creation of a cone availability index to more accurately assess availability; (2) analysis of the fungi that grow symbiotically with whitebark pine, since the health and survival of the pine and the fungi are closely related; (3) monitoring of additional transects in wilderness areas southeast, east, north, and west of YNP; (4) statistical analysis to determine whether GYE grizzly bear mortality correlates more closely with annual variation in whitebark pine abundance or with management practices; and (5) evaluation of the abundance and behavior of red squirrels regarding pine nut storage and the subsequent consumption of those nuts by grizzly bears. A peer-reviewer suggested analyses comparing the vital rates of grizzly bears that feed on whitebark pine to the vital rates of those that do not.

Response—We agree with the comments that whitebark pine will eventually regenerate and ameliorate the losses that have occurred; if the whitebark pine decline was negatively affecting grizzly bears, then the population would not have continued to increase over the same time period as their decline; and increased cone production on the surviving whitebark trees may be temporary. As for the sources of decline in whitebark pine, we note that blister rust, to which the newly planted trees are resistant, is a low source of mortality that primarily affects younger age classes while mountain pine beetle is the greatest source of mortality, primarily among older age classes. See IGBST 2013 for an overview of factors associated with whitebark pine decline. We provide this background to indicate that blister rust resistant trees are not the panacea for ensuring the availability of this food item in the long term. However, more relevantly, substantial evidence to date indicates that whitebark pine is not a critical food resource for bears; rather, whitebark pine is a high-calorie food source that is used by grizzly bears when and where available, as part of a dynamic diet that varies substantially from individual to individual, from season to season, and depending on location within the ecosystem (IGBST 2013, pp. 16–17); see Issue 99.

Approximately 75 percent of mature, cone-producing whitebark pine trees have experienced mortality since 2002, according to an opportunistic sample based on cone production transects conducted by the IGBST since 1980 (see

IGBST Annual Reports). However, mortality is much lower in younger age classes and recruitment is healthy, according to monitoring conducted through the NPS Inventory and Monitoring Program (Greater Yellowstone Whitebark Pine Monitoring Working Group 2016, pp. 6–7). Despite widespread mortality, whitebark pine cone production was good in 2016, and in several other years since the decline peaked around 2009. Moreover, grizzly bears still widely used this resource in good production years. It is impossible to predict at this time whether whitebark pine will still exist as a functional resource for grizzly bears in the future. Regardless, even if whitebark pine were to disappear from the ecosystem altogether, or becomes functionally non-existent for bears, the best available data residing in the Food Synthesis Report's (IGBST 2013, entire) research projects indicate that grizzly bears have shown substantial resilience to changing food sources and, so far, are able to find alternative food resources.

The IGBST conducted a comprehensive study, using available data, to address eight relevant research questions regarding the potential effects of whitebark pine decline on grizzly bears. Several of those questions also addressed issues related to other foods, as well as the ultimate measure of how individuals are responding to changes in food resources, body mass and body condition. See Issue 99. While there will always be new research questions to address and the IGBST is currently pursuing several new hypotheses associated with this theme, many of the commenters' suggestions cannot be addressed with current data, are not relevant, or do not seem to use the scientific principle of ''preponderance of evidence.'' For example, the suggestion regarding the 1988 fires ignores the observation that the period of most robust grizzly bear population growth (4 to 7 percent) occurred shortly after the fires, through the entire decade of the 1990s (see Issue 61).

The changes in vital rates actually started prior to or at the start of whitebark pine decline, as documented in van Manen *et al.* (2016, pp. 307–308). Decline of whitebark pine (as measured in change of tree canopy cover) was directly considered in the analyses of van Manen *et al.* (2016, p. 308) but, unlike bear density, did not show a relationship with vital rates. The population size in the DMA has been relatively constant for the past 15 years, with no evidence of a decline over that time period. The year 2016 represents almost a decade beyond the peak of whitebark pine decline and about 7 years since the mountain pine beetle epidemic starting waning (see IGBST annual whitebark pine monitoring reports: *https://www.usgs.gov/centers/norock/science/igbst-whitebark-pine-cone-production-annual-summaries?qt-science_center_objects=1#qt-science_center_objects*). See Issue 97 for more information. The IGBST has consistently cautioned that the findings from their Food Synthesis Report support the interpretation that grizzly bears were able to respond to changing food resources *so far.* Future conditions may change these relationships, and the adaptive management approach presented in the 2016 Conservation Strategy is designed to allow managers to respond to such changes in a timely manner. However, the previous predictions from the IGBST's 2013 Food Synthesis Report, and underlying research, have been validated over time.

The interpretation that Costello *et al.* (2014) only detected a decline in use of whitebark pine at the end of her study is incorrect; Costello *et al.* (2014, p. 2010) detected a steady decline in selection of whitebark pine habitat over the entire period of 2000 to 2010, and by the end of that period the selection index indicated that bears used whitebark pine stands in proportion to their availability. Based on these findings, the authors concluded that there *was* a population-level effect of a decrease in habitat selection of whitebark pine stands over the 2000 to 2010 time period; careful reading of that paper further shows that these findings supported the hypothesis that whitebark pine seeds are not a highly selected food, but consumed opportunistically as a part of a diverse diet. We agree that, just because NCDE grizzly bears have adapted to whitebark pine loss, this does not mean that GYE grizzly bears will automatically adapt. However, given the preponderance of data from the IGBST, this observation from another ecosystem is supportive of the conclusions and interpretations presented by the IGBST. There is currently no data on the long-term future of whitebark pine in the GYE. Environmental conditions may, or may not, change dramatically in the long term, and scientists are limited in their ability to reliably examine the potential effects of such changes. This is why the 2016 Conservation Strategy presents an adaptive management approach that is informed through scientific monitoring and research, with appropriate measures to timely adapt management as needed.

The comment about potential future impacts of higher human-caused mortality to grizzly bears in years of low whitebark pine production has received much attention but is misleading. Costello *et al.* (2014, p. 2014) specifically addressed this issue:

> . . . . bears were not necessarily compelled to use less secure habitats as a direct response to WBP decline. On average, 48% of fall ranges were comprised of secure habitat outside of WBP forests, indicating most bears had ample opportunities to use secure habitats, even in the absence of WBP foraging. Consequently, most bears selected for secure habitat, irrespective of the intensity of WBP use. Among our sample of bears with WBP habitat within their fall range, 13% used ranges entirely within national parks, 27% used ranges that encompassed ≥95% secure habitat, and 47% selected for secure habitat when nonsecure habitat was present in their range. In other words, only the remaining 13% selected for nonsecure habitat. These results strengthen the supposition put forth by Schwartz *et al.* (2010) in their analysis of hazards to Yellowstone grizzly bear survival. Although these authors found that bears shifted to lower elevations during years of poor WBP production, they concluded that this elevation shift did not itself predispose bears to increased mortality. Instead, they found that bears shifting to lower elevations that had been altered by humans were exposed to more risk, whereas those bears shifting to lower elevations in secure habitat were not subject to increased risk.

Several of the suggestions for additional analyses are useful. However, the symbiotic connections between fungi and whitebark pine, although of interest, would best be studied by forest ecologists, rather than IGBST. The IGBST previously examined (Schwartz *et al.* 2006b, pp. 1–2) relationships of several vital rates with annual variation in whitebark pine cone production. Whereas those analyses indicated some statistical associations of vital rates (litter size, survival of independent-aged bears) with annual variation in whitebark pine cone production, they did not include metrics of availability of whitebark pine in home ranges of individual bears included in the analyses. Although statistical relationships were observed, biological effect sizes were small and somewhat confounded by other factors, such as whether bears were in the core versus the periphery of the ecosystem. Analyses by van Manen *et al.* (2016, entire) partially addressed what is suggested in this comment; they examined vital rates using an individual covariate based on spatiotemporal index of decline in canopy cover of whitebark pine habitat since 2000 (thus, providing an index of mortality). The index was weighted by the proportion of mapped whitebark pine within the activity ranges of bears. They examined survival of independent bears, cubs, and yearlings, as well as reproductive

transition using this covariate; results showed no associations of whitebark pine decline with these vital rates; rather, lower survival of cubs and, to a lesser degree lower reproductive transition from having no cubs to having cubs, were associated with an index of bear density. Thus, although analysis of vital rates for bears without whitebark pine in their home ranges has not been conducted exactly as proposed, extensive analyses previously conducted by the IGBST have addressed various aspects of the basic relationship in this comment.

Issue 104—Commenters opined that ungulates have become a more prominent part of grizzly bear diets in recent years, as other food sources have declined (especially whitebark pine and cutthroat trout), noting that male and female bears now eat more comparable amounts of meat. Commenters also asserted that we incorrectly assumed grizzly bears do not depend on bison from the Northern Range herd (which is experiencing a population increase) because of Fortin *et al.* (2013a) findings that grizzly bears do not frequently feed on bison in the Central herd (which is experiencing a population decline).

We received many comments from both the public and peer-reviewers regarding recent declines in the availability of ungulates as a food source, and potential effects on grizzly bear populations, which we inadequately considered in our proposed rule. These comments included that: (1) All elk herds in the GYE (except the Upper Madison herd) have declined due to increased calf depredation, drought, chronic wasting disease, and human hunters; (2) effects on elk from hunters are synergistic because hunters preferentially target top breeding individuals (Vucetich *et al.* 2005, Wright *et al.* 2006, Mallonee 2011); (3) we neglected to include a discussion of bison population trends and, thus, did not account for the impacts to grizzly bears of planned herd reductions in various bison management plans; and (4) winter severity and length have gone down with climate change, which has decreased the availability of winter-killed carrion in the spring.

Commenters also expressed concerns regarding the potential side-effects of grizzly bear reliance on ungulates as a food source, such as: (1) Declines in cub and yearling survival rates due to more deadly confrontations with other predators, including adult male grizzly bears; (2) increased conflicts with ranchers and hunters; and (3) consumption of food sources that are unsuitable for meeting female grizzly bear reproductive needs.

Commenters also suggested we include additional monitoring and analysis, such as: (1) Data on the numbers of elk and bison in various ecosystem herds; and (2) information on the historical, current, and future effects of predation by grizzly bears and wolves, winter severity, disease, and habitat availability on ungulate abundance. Peer-reviewers suggested that we should (1) conduct an analysis of cub survival from 2002 to 2014 to assess predator-prey relationships, which may have a time-lag in detectability; and (2) estimate the amount of biomass left by ungulate hunters and available to grizzly bears instead of counting the number of hunters.

Response—The availability of ungulate prey such as elk and bison is not a threat to the persistence of GYE grizzly bears, and future changes in prey abundance are not expected to change this conclusion. There have been documented declines in some ungulate populations, while others have increased, and we expect fluctuations in ungulate populations to continue in the future. As generalist food consumers, GYE grizzly bears have demonstrated flexibility in meeting their dietary needs and are accustomed to successfully finding alternative natural foods. The population decline in the northern elk herd has been attributed to a variety of factors including severe winters, drought, hunter harvest, and increased predation on elk calves by grizzly bears, black bears, and wolves. However, it is noteworthy that during this same time period the grizzly bear population has continued to increase. This situation suggests that there is no detectable cause and effect relationship between elk population declines and grizzly bear population trends. See Issues 97, 98, and 99 for more information about food sources and grizzly bear demographics.

The GYE grizzly bear consumes bison primarily as winter-killed carrion, but also opportunistically kills calves and weakened adults. The Yellowstone bison population size has remained within the IBMP's recommended range of 2,500 to 4,500 bison since the year 2000, with the exception of 2005 and 2007 years when numbers exceeded 4,500. Therefore, we do not anticipate that bison as a potential food source will be a limiting factor for GYE grizzly bears in the future. Please see Issue 100 and the *Unusual or Unique Ecological Setting* section in the DPS section of the final rule for further discussion on the use of bison by grizzly bears.

Areas with a high risk of grizzly bear mortality due to repeated conflict with humans or livestock are not considered suitable habitat and are not included in our quantification of habitat available to meet the needs of a recovered grizzly bear population. See Issue 40.

As previously stated, the 2016 Conservation Strategy will continue monitoring multiple indices, including production and availability of all major foods and grizzly bear vital rates—survival, age at first reproduction, reproductive rate, mortality cause and location, dispersal, and human-bear conflicts. These data will allow managers to use an adaptive management approach that addresses poor food years with responsive management actions such as limiting grizzly bear mortality, increasing I&E efforts, and long-term habitat restoration as appropriate. The continued monitoring of these multiple indices will maintain the recovered population.

Issue 105—One commenter suggested that huckleberries (*Vaccinium ssp.*) are currently less abundant as a result of warming temperatures and a persistent drought pattern in the GYE. Another commenter referenced McLellan (2015) to warn that the effects of huckleberry decline on grizzly bear populations could be delayed; the grizzly bear population in Canada and northern Montana did not start to decline until 11 years after the huckleberry abundance started to drop.

Response—*Vaccinium* berries historically have not been a significant dietary component of the GYE grizzly bear diet, occurring in only 4.9 percent of the 11,478 scats analyzed from 1943 to 2009 (Gunther *et al.* 2014, p. 64). Craighead *et al.* (1995, p. 235) found that berry availability was inconsistent across the GYE and between years. In addition, some climate models for the GYE predicted an increase in spruce-fir dominated forests at mid- to high-elevations (Schrag *et al.* 2007, pp. 9–10), which are associated with *vaccinium* berry species (in their entirety: Pfister *et al.* 1977; Steele *et al.* 1983). Low-elevation Douglas-fir and lodgepole pine forests, which are commonly associated with dwarf huckleberry, may also expand under some climate models (Rice *et al.* 2012, p. 31). Please see Issue 36 for discussion of lag effects.

The extent to which natural foods will change across the landscape and the resulting effects on bears is impossible to calculate with any degree of certainty. See Issue 98. Future food source availability and the possible grizzly bear reaction to those possible future changes are discussed under *Factor E,* above, and in the Issues 99 to 104 above.

Climate Change Issues (Factor E)

Issue 106—We received many public and peer-review comments regarding effects to grizzly bears as a result of climate change. Overall, public commenters asserted that our discussion of climate change was flawed or inadequate because: (1) We reviewed the current literature regarding climate change but did not link effects to grizzly bears or their habitat; (2) we should consider and better describe the future impacts from climate change, despite the fact that the exact extent of impacts is unknown; (3) the ''downscaled'' projection we used to analyze climate change may have underestimated impacts; (4) we should have assessed impacts from the changing hydrological regime; and (5) we need to consider climate change impacts on Alaskan grizzly bears, since they are our ''fall-back grizzly bear supply.'' Commenters suggested that the impacts of climate change in YNP are already clear since conditions have become warmer and drier with ''30 fewer days per year with snow on the ground'' and ''80 more days each year above freezing.''

Commenters mentioned the many potential ways climate change could continue to affect grizzly bears and increase human-bear conflicts (Servheen and Cross 2010), including: (1) Reduction of snowpack and shortening of the winter season, which could affect the timing and success of denning, potentially reducing reproductive success and increasing conflict; (2) less snowpack could result in fewer avalanche chutes, preferred spring and summer habitat for grizzly bears; (3) the effect of drought on death rates; (4) increased frequency and extent of fire could alter plant and animal composition (Westerling *et al.* 2011) and affect the frequency of human-grizzly bear interactions and conflicts; (5) the potential of hyperthermia to limit foraging capabilities for grizzly bears in areas of decreased forest cover (Pigeon *et al.* 2016); and (6) further reductions in food sources. One commenter asked for clarification on why surveyed biologists believe that climate change is not a threat to grizzly bears, while another commented that climate change ''may even make habitat more suitable and food sources more abundant.'' Citing the 2016 court ruling requiring the Service to more adequately consider and address the threats of climate change on wolverines, commenters suggested that declaring that climate change is not affecting grizzly bears was similarly nonsensical and ''arbitrary and capricious.'' Commenters suggested that managers could mitigate impacts from climate change by creating corridors for migration to new habitats or by keeping the bears protected under the Act. One commenter suggested that any decisions about delisting need to be postponed until an ''independent scientific review'' can look at the impacts of climate change on grizzly bears.

Commenters and peer-reviewers suggested that several issues related to climate change require monitoring, such as: (1) Monitoring and modeling potential impacts of climate change on habitat suitability and the abundance and distribution of grizzly bear food in relation to temperature and moisture dependence; (2) monitoring possible effects of climate change on grizzly bear vital rates; and (3) monitoring for emerging diseases since the frequency of diseases and parasites will likely change in the context of climate change.

Response—Based on workshops involving grizzly bear experts, Servheen and Cross (2010, p. 4) concluded that ''grizzly bears are opportunistic, omnivorous, and highly adaptable and that climate change will not threaten their populations due to ecological threats or constraints.'' More recent research by IGBST, including the Report and peer-reviewed publications associated with the Food Synthesis project, support this conclusion. Because of the substantial degree of uncertainty regarding the specific consequences of climate change on ecological communities (some of which may perhaps be positive), the questions and suggestions from the commenters are mostly speculative and are difficult to address based on current data, let alone with regard to long-term impacts. The Service must make its listing/delisting decisions based solely on the best available scientific data. Our current understanding of that data indicates that the GYE grizzly bears are not and will not be threatened by the effects of climate change now or in the foreseeable future. However, continued monitoring and research, in combination with an adaptive management approach, will ensure that direct or indirect effects of climate change on grizzly bear ecology are detected and addressed in a timely manner.

Other Potential Threats (Factor E)

Issue 107—Some commenters raised questions about wolves and their effects on grizzly bears in the GYE. One commenter asserted that wolves have been reintroduced too recently to determine the relationship between wolves and bears in the ecosystem. One commenter stated that wolves have decreased the availability of spring carrion, which disproportionately affects female grizzly bears, and have decreased elk populations. One commenter noted that wolves have been known to kill grizzly bear cubs, though this phenomena is very difficult to detect and quantify. One comment maintained that female grizzly bears rarely usurp wolf kills (Gunther and Smith 2004).

Response—Prior to the extirpation of wolves from Yellowstone in the mid-1920s, grizzly bears and wolves coexisted for several thousand years. Post wolf reintroduction, there have been documented declines in some ungulate herds; however, overall, prey numbers remain healthy and some ungulate herds have increased (Barber-Meyer *et al.* 2008, p. 23). However, these interactions usually do not result in any injury to either bears or wolves and do not threaten the grizzly bear population. Models and field investigations suggest that, since they were reintroduced to the GYA in 1995, wolves have had little effect on ungulate availability to GYE grizzly bears (Wilmers *et al.* 2003, pp. 914–915; Barber *et al.* 2005, p. 43; Vucetich *et al.* 2005, p. 259). This issue is discussed in more detail under *Factors B and C Combined and E* in this final rule.

Issue 108—We received comments from both the public and peer-reviewers requesting increased effort, time, and money towards public I&E campaigns regarding coexistence with grizzly bears, potentially using phone applications. One commenter was concerned that the Service would reduce I&E efforts post delisting; conversely, other commenters believed that we over rely on our efforts to inform and educate the public about potential grizzly bear encounters, and that I&E, specifically bear identification training, has failed to reduce human-caused mortality from hunters. Several commenters believed that control and reduction of the grizzly bear population, in addition to outreach, would be essential to long-term conservation of grizzly bears in the GYE. Commenters suggested that the three States' grizzly bear management regulations require all hunters to take and pass a bear identification training, which would instruct on distinctions between black bears and grizzly bears, identification of grizzly bear age, distinguishing between male and female bears, finding cubs, proper food storage, and the use of bear spray. One commenter suggested that no hunting should be allowed in the DMA until hunters in all three States can show 99 percent proficiency with bear identification.

Response—All the Federal and State agencies charged with management of

grizzly bears or their habitat in the GYE recognize the importance of outreach and I&E efforts to the long-term conservation of the GYE grizzly bear population. The details related to implementing effective outreach efforts and preventing and responding to grizzly bear-human conflicts are in the final 2016 Conservation Strategy (YES 2016a, pp. 86–95) and the State management plans (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 13–18; MFWP 2013, pp. 53–59, 65–69; WGFD 2016, pp. 20–27). Over two-thirds ($3,293,817 of $4,991,123) of the anticipated costs of managing the GYE grizzly bear population are for managing grizzly bear-human conflicts and I&E efforts. This level of commitment by responsible agencies demonstrates their understanding that I&E efforts and conflict management and prevention are crucial elements of maintaining a healthy GYE grizzly bear population and help ensure that mortality limits are not exceeded. Although the effectiveness of I&E, specifically bear education training, in reducing human-caused mortality from hunters has not been formally evaluated, they are credited with increasing tolerance for grizzly bears and reducing conflicts, especially as bears have expanded into new areas where people are not as educated about living in bear country; these efforts are ongoing, and total mortality within the DMA will be maintained within the mortality limits set forth in the final rule and the 2016 Conservation Strategy. The I&E team currently uses modern media, such as YouTube and Facebook, to help educate the public. In addition, the I&E team continuously evaluates and adapts their programs to effectively educate people that live and recreate in grizzly bear habitat. The States also all have bear management specialists who dedicate a majority of their time on outreach and education to educate people about living, working, and recreating in bear country.

The 2016 Conservation Strategy prioritizes outreach and education, and the State plans also contain direction on ways, to minimize grizzly bear-human conflicts (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, p. 15; MFWP 2013, pp. 65–69; YES 2016a, pp. 86–95; WGFD 2016, pp. 26–27). Although the States do not currently require hunters to carry pepper spray, it is strongly encouraged in hunter education courses and other educational materials. Elk hunters in GTNP are required to carry bear spray, and this may prove to be a research opportunity to quantify how much, if any, this requirement reduces grizzly bear conflicts with elk hunters.

Between 2002 and 2014, 37 percent (115 of 311) of human-caused grizzly bear mortalities were related to hunting (defense of self or others and mistaken identity kills) (Haroldson 2014a, 2017c, *in litt.;* Haroldson and Frey 2015, p. 26), so an increase in backcountry user awareness would be beneficial. The affected States of Wyoming, Montana, and Idaho have cooperated with the Service to address conflicts between grizzly bears and hunters through extensive I&E programs. Please see Issue 109 for further details on the States' I&E programs. Idaho and Wyoming provide a voluntary bear identification test online, and all three States include grizzly bear encounter management as a core subject in their basic hunter education courses.

Issue 109—Several commenters recommended that the Service do more research on attitudes, social tolerance, perspectives, and human behavioral intentions before delisting. A commenter opined that social support is important to resolving grizzly bear conflicts, rather than compensation programs for losses. Another commenter felt that if the Service concludes that hunting increases social tolerance, the hunting quotas and locations should be arranged so bears are allowed to disperse through specified corridor zones without being hunted. While several commenters suggested delisting could significantly improve tolerance of the grizzly bear in the GYE, others stated that social acceptance of grizzly bears will not improve if we allow more discretion in bear management; instead, the commenter suggested that increased acceptance will come from rigid enforcement of laws and expanded tourism.

Response—Public support and human attitudes are discussed at length under *Factor E* of the final rule. Human attitudes toward grizzly bears, specifically, the resulting human-caused mortality, was identified as a primary cause of population decline in the species' 1975 listing under the Act (40 FR 31734, July 28, 1975). Public support is paramount to any successful large carnivore conservation program (Servheen 1998, entire; Alberta Grizzly Bear Recovery Team 2008, p. 2), and human attitudes still play a pivotal role in grizzly bear conservation. Although attitudes about grizzly bears vary geographically and demographically, we have seen an improvement in public perceptions and attitudes toward grizzly bears in the last several decades, even among traditionally conflict-related communities, like the ranching industry (Kellert *et al.* 1996, pp. 983–986). Grizzly bear-human conflicts often lead to grizzly bear mortalities, either legally in self-defense or a management removal, or illegally through vandal killing. Effective I&E programs increase public understanding of grizzly bear biology, behavior, and recovery efforts, which in turn reduces grizzly bear-human conflicts and grizzly bear mortalities while increasing human safety. Many people who live and work in occupied grizzly habitat have significantly contributed to increasing social tolerance through voluntary use of tools and techniques aimed at reducing conflict. This social tolerance has been built in large part by proactive outreach and immediate professional response to conflict incidents arising from the presence of bears.

Public outreach presents a unique opportunity to effectively integrate human dimensions of wildlife management into comprehensive programs that can modify societal beliefs about, perceptions of, and behaviors toward grizzly bears. Attitudes toward wildlife are shaped by numerous factors including basic wildlife values, biological and ecological understanding of species, perceptions of individual species, and specific interactions or experiences with species (in their entirety: Kellert 1994; Kellert *et al.* 1996).

The I&E programs teach visitors and residents about grizzly bear biology, ecology, and behavior, which enhances appreciation for this large predator by dispelling myths about its temperament and feeding habits. Effective I&E programs have been an essential factor contributing to grizzly bear conservation since its listing in 1975. Being aware of specific values common to certain user groups allows I&E materials and workshops to be tailored to their specific concerns and perceptions. By providing general information to visitors and targeting specific user groups living and working in grizzly bear country, coexistence between grizzly bears and humans can be accomplished. Traditionally, people involved in resource extraction industries (*i.e.,* timber harvest, mining, ranching, and hunting) are the largest opponents to land-use restrictions that place the needs of the grizzly bear above human needs (Kellert 1994, p. 48; Kellert *et al.* 1996, p. 985). Surveys of these user groups have shown that they tolerate large predators when they are not seen as direct threats to their economic stability or personal freedoms (Kellert *et al.* 1996, p. 985).

State wildlife agencies recognize that the key to preventing grizzly bear-human conflicts is providing I&E to the public and connecting the public with the right resources to prevent conflicts (Idaho's Yellowstone Grizzly Bear Delisting Advisory Team 2002, pp. 13–14; MFWP 2013, pp. 49–51, 65–68; WGFD 2016, pp. 26–27; YES 2016a, pp. 92–95). This outreach is the most effective long-term solution to grizzly bear-human conflicts and is paramount to ongoing grizzly bear survival and successful coexistence with humans so that the measures of the Act are no longer necessary. All three affected States wildlife agencies (IDFG, MFWP, and WGFD) and associated partners (*e.g.,* Grizzly Bear Outreach Project) have been actively involved in I&E outreach for over a decade. In addition, the grizzly bear management plans developed by MFWP, WGFD, and IDFG contain chapters detailing efforts to continue current programs and expand them when possible.

States are committed to continuing these public outreach and conflict response efforts to help maintain and expand that tolerance. Compensation programs are another tool that helps with this effort, since livestock producers who suffer losses from bears are likely to be more tolerant of them if they are compensated for losses caused by grizzly bears. Based on recent experiences with wolves in Idaho and Montana, social tolerance for wolves improved as both States implemented an adaptive management approach to managing conflict during the post-delisting monitoring period. By building and maintaining social tolerance, the recovered bear population will continue to be maintained.

Ultimately, the future of the grizzly bear will be based on the people who live, work, and recreate in grizzly bear habitat and the willingness and ability of these people to learn to coexist with the grizzly bear and to accept this animal as a cohabitant of the land. Other management strategies are unlikely to succeed without effective and innovative public I&E programs. The primary goals of public outreach programs are to proactively address grizzly bear-human conflicts by educating the public about the root causes of these conflicts and providing options to prevent them. By continuing to increase awareness about grizzly bear behavior and biology, we are confident that the current and planned I&E efforts will reduce the negative outcomes of human-grizzly bear encounters such that the GYE grizzly bear population is no longer threatened by these activities, nor likely to become so in the foreseeable future.

Issue 110—A commenter requested that the Service address the high prevalence of developmental malformations in newborn grizzly bears but did not provide any information about the source of these potential malformations.

Response—To our knowledge, there have been no documented instances of high rates of developmental malformation in newborn grizzly bear cubs in the GYE or elsewhere.

Cumulative Impacts of Threats Issues

Issue 111—Both commenters and peer-reviewers expressed concern that the synergistic effects of climate change, changing food availability, invasive species, increased human-caused mortality, energy development, problematic livestock husbandry practices, increased regional human populations, and disease are unknown and may not be detected for decades. The commenters and peer-reviewers recommended a more complete analysis of this suite of impacts and consideration of their potential interactions.

Response—Our assessment of threats considered potential risk factors individually and cumulatively (see the *Cumulative Effects* section of the proposed and final rule). Our threats assessment is organized sequentially, consistent with how section 4(a) of the Act is organized. We then discuss the overall finding, which considers the cumulative impacts of all potential threat factors. We considered and weighed the cumulative effects of all known and reasonably foreseeable threat factors facing the population when reaching the conclusion that the grizzly bear population in the GYE no longer meets, and is unlikely to meet in the foreseeable future, the definition of a threatened species. When considering the population's recovered status, it is important to remember that the recovery criteria require a minimum population size of 500 to maintain short-term genetic health, occupancy of females with young to ensure adequate distribution, and sustainable mortality limits to maintain the population around the period of stability from 2002 to 2014. After delisting, Idaho, Montana, and Wyoming have committed, through a Tri-State MOA, State management plans, and regulations, to manage mortality limits to maintain a recovered GYE grizzly bear population. The GYE grizzly bear population has been biologically recovered for at least a decade, and there is evidence that grizzly bears within the GYE DMA have reached carrying capacity.

Overall, the GYE grizzly bear population's current and expected abundance and geographic distribution (occurring both inside and outside the DMA and occurring across multiple management jurisdictions) provides the GYE grizzly bear population with substantial representation, resiliency, and redundancy (see *Significant Portion of its Range* discussion for further details). These factors provide us with confidence the population can continue to be viable in the face of the types of individual, as well as cumulative, effects mentioned in the above comments. For example, there is no evidence of negative population-level effects on grizzly bears, including accounting for a lag effect, as a result of declines in whitebark pine, cutthroat trout, or both. While it is potentially feasible that the GYE grizzly bear population may be at risk of such catastrophic events such as a cataclysmic eruption underneath YNP devastating the GYE ecosystem, such an event is extremely unlikely within the foreseeable future (see the *Catastrophic Events* section of the final rule).

Distinct Population Segment and Significant Portion of the Range Issues

Issue 112—Several commenters found our approach to the DPS designation logical and consistent with our authority under the Act and stated that failing to utilize this authority would devote resources to a recovered population and unnecessarily punish the States and communities that participate in recovery. Conversely, a number of other commenters asserted that designating the GYE population as a DPS violated the law because we are purportedly not allowed to designate a DPS for the purposes of delisting it. Commenters alleged that no provision in the Act allows this process, and our approach (designating a DPS for the purposes of delisting) has repeatedly been rejected by Federal Courts. Another commenter thought delisting should not occur until DPSs were designated across the entire range of the subspecies. Commenters took issue with our position that the designation of the DPS in the proposed delisting rule is consistent with the Service's past practices.

Response—Section 4(a)(1) of the Act authorizes the Service at any time to determine whether a species, which by definition includes a DPS, is endangered or threatened. Section 3(16) of the Act defines a ''species'' as including any subspecies of vertebrate fish or wildlife which interbreeds when

mature. In addition, section 4(c)(1) of the Act authorizes the Service to revise the List to reflect recent determinations made under section 4(a) by directing the Service to ''from time to time revise each list . . . to reflect recent determinations, designations, and revisions.'' Nothing in the Act suggests that the Service is precluded from making such determinations and revisions with respect to a subspecies or DPS that is part of a larger listed species. Therefore, the Service is acting within its authority in determining that the GYE grizzly bear DPS is neither endangered nor threatened and revising the List by removing the GYE grizzly bear DPS. Furthermore, while in some situations it may be appropriate to designate multiple DPSs simultaneously, the lack of such requirement provides useful flexibility, allowing the Service to subsequently list or delist DPSs when additional information becomes available or as the conservation status of the taxon changes. We disagree with commenters' contentions that the action taken in this final rule is inconsistent with the Service's past practice. Although a few of our examples predate the DPS policy, the authority to list and delist DPSs had been clearly established since the 1978 amendments to the Act. In addition, two of the examples have been finalized since publication of our proposed rule. Please see the *Distinct Vertebrate Population Segment Policy Overview, Past Practice and History of Using DPSs,* and *Distinct Vertebrate Population Segment Analysis* sections of this rule for further explanation of our DPS policy, history, and analysis.

Issue 113—The States supported our analyses and concurred that the GYE population qualifies as a DPS under our DPS policy. However, others claimed that even if we were allowed to designate the GYE as a DPS at the time of delisting, our analysis did not adequately justify such a designation. First, in the opinion of some commenters, the Service's DPS policy requires that we consider three factors when determining whether a DPS designation is valid—discreteness, significance, and status. The commenters argued that our DPS policy allows designation of a DPS only if the DPS alone qualifies for listing as either endangered or threatened; this is the ''status'' portion of the DPS designation analysis. These commenters contended that we considered only discreteness and significance and left out the status portion of the analysis. We instead, they argued, ''rolled'' the status analysis into the proposed rule's five-factor analysis. These commenters suggested that if we had followed the ''requirement'' that the status analysis be done in the context of the DPS designation, we could not have designated the DPS because we would have concluded that the population does not qualify as threatened or endangered.

Second, a few commenters seemed to have misunderstood our analysis. One stated that our conclusion that the GYE DPS does not qualify as an endangered or threatened species meant that the GYE DPS does not qualify as a ''species'' under the Act. Another suggested that because the grizzly bear is currently listed as a DPS (lower 48 States) we cannot designate the GYE population as a DPS because this would be creating a DPS of a DPS.

Third, commenters weighed in on the geographic scope of our DPS designation. Some commenters thought we drew the DPS boundary appropriately. Others thought we should have defined it more broadly to include: (1) Additional unsuitable habitat where bears from the GYE population might roam; and (2) additional suitable habitat deemed necessary for connectivity to other populations of grizzly bears. Still others thought we should have conducted additional analyses to evaluate the importance of unsuitable habitat to GYE grizzly bears including information on: (1) How much time grizzly bears spend in unsuitable habitat; (2) why grizzly bears spend time in unsuitable habitat; (3) how much time researchers spend looking for bears in unsuitable habitat; and (4) the extent to which bears need this habitat as corridors between areas of suitable habitat. Another commenter suggested that the DPS should include all grizzly bears in Montana since all grizzly bears in the State of Montana should be removed from the lists of threatened and endangered species.

Fourth, several commenters wanted greater certainty about our intentions for grizzly bear recovery in the remainder of the listed entity (lower 48 States outside of the GYE DPS). Some stated that, prior to taking action on any individual population, the Service must designate multiple DPSs encompassing the entire range of the subspecies, set recovery goals for each DPS, and evaluate the status of each DPS for listing. Others recommended that we explain our intentions for the remainder of the grizzly bear listed entities in a notice of proposed rulemaking, which should set forth a timeline for initiating and completing such reevaluation and allow solicitation of public comment on possible ways the remainder of the listed entity could be reclassified.

Response—Our process for determining that the GYE grizzly bear population is a valid DPS is entirely consistent with the Services' joint 1996 DPS Policy (61 FR 4722, February 7, 1996). The 1996 DPS Policy identifies two elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the species (or subspecies) to which it belongs; and (2) the significance of the population segment to the remainder of the species (or subspecies) to which it belongs. Our policy clearly states that if a population segment is both discrete and significant then it is a DPS (61 FR 4725, February 7, 1996). The GYE grizzly bear population meets both of these elements (see *DPS Analysis*) and, therefore, is a DPS.

Because the GYE grizzly bear population is a DPS based on the ''discreteness'' and ''significance'' qualifications, we must then evaluate the DPS's conservation status in relation to the Act's standards for determining whether the DPS is endangered or threatened. The authority and standards for conducting this status determination comes directly from section 4(a)(1) of the Act and the Service's implementing regulations, not the DPS policy. In other words, the outcome of the discreteness and significance analyses determines if a population is a DPS. Then the outcome of the section 4 analysis on that DPS determines if the DPS warrants protections under the Act. This final rule adheres to all of the required analyses for identifying the GYE grizzly bear population as a DPS. And, therefore, per section 4 of the Act, we have the authority to consider if the GYE grizzly bear DPS is endangered or threatened; and if it is neither, as we have determined here, to revise the lower-48 grizzly bear listing to remove the DPS from Federal protection.

Our recognition of the GYE grizzly bear DPS does not create a DPS of a DPS. A population's discreteness and significance determinations are based on its discreteness and significance to the taxon (species or subspecies) to which it belongs; in this case the taxon is the subspecies *Ursus arctos horribilis* (see *DPS Analysis*). Therefore, consistent with our 1996 DPS Policy, the GYE grizzly bear is a DPS of *Ursus arctos horribilis* and not of the lower-48 States listing.

As stated in the proposed and final rules, when delineating the boundary of the GYE grizzly bear DPS, we focused on including sufficient habitat that was capable of supporting grizzly bear reproduction and survival now and in the foreseeable future. We have defined

''suitable habitat'' for grizzly bears as areas having three characteristics: (1) Being of adequate habitat quality and quantity to support grizzly bear reproduction and survival; (2) being contiguous with the current distribution of GYE grizzly bears such that natural recolonization is possible; and (3) having low mortality risk as indicated through reasonable and manageable levels of grizzly bear mortality. The GYE grizzly bear population is the most studied grizzly bear population in the world, and we are confident that the suitable habitat encompassed within the area delineated as the GYE DPS is more than sufficient to maintain the recovered population now and in the foreseeable future. For more information on these analyses, please refer to the *Suitable Habitat* and *Distinct Vertebrate Population Segment Analysis* sections of this rule. With respect to the assertion that the entire State of Montana be included in the GYE DPS, there is no biological basis for considering all grizzly bears in the State of Montana as part of the GYE DPS. When this rule becomes effective, all areas in the lower 48 States outside of the GYE DPS boundary will remain protected as threatened under the Act.

For more than 30 years, the Service has strived to maintain transparency in our grizzly bear recovery program. The Service's grizzly bear Recovery Plan, first approved in 1982 and revised in 1993, and its supplemental documents (USFWS 1982, 1993, 2007*a,* 2007*b,* 2016, 2017) identify distinct Recovery Zones and unique demographic parameters for six different grizzly bear populations with the expressed intent that these individual populations would be delisted as they each achieve recovery (USFWS 1993, pp. ii, 33–34). Given this history, it is not an efficient use of our limited resources to initiate a rulemaking process to revise the lower-48 States listing. Such a rulemaking would provide no more information about our intentions for grizzly bear recovery than the parameters and documents already guiding our existing grizzly bear recovery program.

Issue 114—While some commenters found our analysis of the best available science to support a determination that the population is discrete, others questioned the strength of our discreteness analysis. Some took issue with our determination that the GYE population is ''markedly separated'' from other populations of grizzly bear. Commenters contended that it is well accepted in the scientific community that the GYE grizzly population will need to be well connected with other populations across the western landscape in order to foster the species' true recovery. Commenters found it illogical to use the GYE population's current lack of connectivity to other grizzly bear populations to justify delisting. They found our position with respect to genetics inconsistent because they contend we make the opposite argument when asserting, in our DPS analysis of significance, that we cannot state with certainty that the GYE grizzly population's genetics differ 'markedly' from other grizzly bear populations.

Response—We have determined that the GYE population is markedly, physically separate from other grizzly bear populations; however, this determination is not our justification for delisting the population. The GYE grizzly bear population is being delisted because we have determined after a thorough analysis of the five threat factors that it is not in danger of extinction now or in the foreseeable future throughout all or a significant portion of its range. Grizzly bears will remain listed in the remainder of the lower 48 States outside of the GYE DPS, and we are committed to pursuing grizzly bear recovery in the five remaining Recovery Zones identified in the 1993 Grizzly Bear Recovery Plan.

We refer to genetic studies estimating heterozygosity in our consideration of discreteness to further support the conclusion that grizzly bears from the GYE are markedly, *physically* separated from other grizzly bears. As we state in the rule, heterozygosity is a useful measure of genetic diversity, with higher values indicative of greater genetic variation and evolutionary potential. High levels of genetic variation are indicative of high levels of connectivity among populations or high numbers of breeding animals. By comparing heterozygosity of extant bears to samples from Yellowstone grizzly bears of the early 1900s, Miller and Waits (2003, p. 4338) concluded that gene flow and, therefore, population connectivity between the GYE grizzly bear population and populations to the north was low even 100 years ago. However, we do not know whether differences in heterozygosity levels between grizzly bears from the GYE and other populations are *biologically* meaningful, and we have no data indicating they are. Therefore, this same information is not sufficient to support a claim that that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

Issue 115—With respect to our DPS analysis of significance, some commenters found our analysis adequately supported our determination of significance. Others found our conclusion that the population's ''loss would represent a significant gap in the range of the taxon'' to be hypocritical because it results in the delisting of the population and, in their opinion, makes loss of the bears more likely. Commenters argued that our DPS significance determination undermines our duty to recover the ''species as a whole'' because it doesn't make sense that we could argue the GYE population's essentiality to the species overall in order to support delisting the bears. Commenters contended that the Service's duty under the Act is to get listed species to a point where the law's protections are no longer required, not undermine recovery efforts for the remainder of the listed entity by using conflicting interpretations of scientific data.

Response—The DPS analysis for significance is intended to determine the biological and ecological significance of the population to the taxon to which it belongs. As specified in the DPS policy (61 FR 4722, February 7, 1996), this consideration of the population segment's significance may include, but is not limited to, the following: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; or (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

Based on public comments, we reevaluated our assessment of the ''unique or unusual ecological setting'' for the GYE grizzly bear and revised our discussion in this final rule. In this case, we determined that the GYE grizzly bear population is significant due to its persistence in an ecological setting unique for the taxon and that loss of the population would result in a significant gap in the range of the taxon (*i.e., Ursus arctos horribilis*). This determination means that the GYE grizzly bear population qualifies as a valid DPS. The GYE grizzly bear population is being delisted because we have determined after a thorough analysis of the five threat factors that this DPS is not in danger of extinction now or in the foreseeable future throughout all or a significant portion of its range. Grizzly bears will remain listed in the

remainder of the lower 48 States outside of the GYE DPS, and we are committed to pursuing grizzly bear recovery in the five remaining Recovery Zones identified in the 1993 Grizzly Bear Recovery Plan.

Issue 116—Commenters expressed discontent with the Service's current interpretation of the phrase ''significant portion of its range'' (SPR) in the Act's definitions of ''endangered species'' and ''threatened species.'' Some commenters did not believe the Service's interpretation is reflective of Congressional intent. Commenters believed that the Service erroneously interpreted ''range'' to mean only the range in which the species currently exists. Commenters thus took issue with the exclusion of historic range from any SPR analysis. Commenters also believed that the Service's threshold for significance was too stringent.

Response—The Service's current interpretation of the phrase ''significant portion of its range'' (SPR) is consistent with the plain language and mandates of the Act and provides clarity as to both the meaning and consequences of the SPR phrase. With respect to the criticism that the Service should have considered lost historical range in our SPR analyses, it is the Service's position that the term ''range'' in the phrase ''significant portion of its range'' is in reference to a species' current range. Thus, to consider lost historical range in our SPR analysis would be inconsistent with this interpretation. We do not separately consider whether lost historical range is an SPR because we already evaluate the effects of lost historical range on the species when we evaluate the status of the species in its current range. Specifically, in our evaluation of current status, we are considering whether, without that portion (*i.e.,* lost historical range), the species is in danger of extinction or likely to become so in the foreseeable future (See discussion under *Factor A,* above). If lost historical range had indeed been an SPR prior to its loss, then, with the loss having occurred, the species should currently be in danger of extinction or likely to become so in the foreseeable future in its remaining current range. Such a determination would then result in the listing of a species throughout its range.

Again, the Service's analysis to determine if a species ''is in danger of extinction'' throughout all or a significant portion of its range denotes a present-tense condition of being at risk of a current or future undesired event. To say a species ''is in danger'' in an area where it no longer exists—*i.e.,* in its historical range where it has been extirpated—is inconsistent with common usage.

Finally, in our SPR analysis we set forth the standard by which a portion of a species' range may be considered significant. It is the Service's position that a portion of the range of a species is significant if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range. We have applied this standard in our final rule.

Issue 117—Several commenters expressed concern about our ''significant portion of its range'' analysis. A commenter expressed concern that the proposed rule relegates grizzly bears to small portions of the lower 48 States and ignores the species' lost historical range in the remainder of the lower 48 States. Commenters specified that our analysis of lost historical range should consider the entire population of grizzly bears across the lower 48 States. Further, assuming that our proposed DPS delisting process is legal, commenters instructed us to also consider lost historical range of the GYE DPS, including an analysis of what constitutes the GYE DPS' historical range, how that compares with the GYE DPS' current range, and whether or not the loss of historical range is significant. They further directed the Service to consider threats in areas where the population is either extirpated or home to only a few individuals; they claimed that it is insufficient to focus analysis entirely on an area where a population persists to support a finding that threats elsewhere are not significant. Commenters noted that many activities that have potentially adverse effects on bears are found only outside of YNP, outside of the PCA, or outside the DMA. They expressed concern that the Service acknowledges some of these threats but discounts their importance. Commenters stated that the standard we seemed to apply (localized threats must threaten extinction of the GYE DPS as a whole) was inappropriate and illegal. They further stated that the Service's SPR analysis ignores the fact that loss of bears in the peripheral areas would result in significant range contraction and that, according to our own policy, such lost range may never be reclaimed or considered in future listing decisions.

Response—This action is specific to the grizzly bear population in the GYE and, therefore, affects the legal status only of grizzly bears within the GYE. In other words, when this rulemaking takes effect, grizzly bears in the lower 48 States occurring outside of the boundary of the GYE DPS will remain listed as a threatened species under the Act. Therefore, consideration and analyses of grizzly bear populations elsewhere in the lower 48 States is outside the scope of this rulemaking.

As stated in our response to Issue 116 above, it is the Service's standard practice to consider the effects of lost historical range on the species when we evaluate the status of the species in its current range. In the case of the GYE DPS, we address historical range in our analysis of suitable habitat. In our discussion we acknowledge that bears historically occurred, although were probably not evenly distributed, throughout the area of the GYE DPS. Many of these habitats are no longer biologically suitable for bears (see Issue 40).

Limited gene flow, as suggested here, would not compromise the required level of discreteness for DPS status, as the DPS policy does not require complete separation of one DPS from other populations, but instead requires ''marked separation.''

As stated previously, it is the Service's standard practice to consider the effects of lost historical range on the species when we evaluate the status of the species in its current range. See discussion under *Factor A,* above. Additionally, our status analysis thoroughly evaluated all potential threats to the population in its current range. It would be inconsistent with Agency current practice to consider threats in areas where the grizzly bear does not currently exist.

Our SPR analysis is consistent with current agency practice. After careful examination of the GYE grizzly bear population in the context of our definition of ''significant portion of its range,'' we determined areas on the periphery of the range warranted further consideration because human-caused mortality risk threats are geographically concentrated there. After identifying these areas, we evaluated whether they were significant and determined they were not significant because, even without the grizzly bears in these areas, the GYE grizzly bear DPS would not be in danger of extinction, or likely to become so in the foreseeable future. These areas will likely never contribute meaningfully to the GYE grizzly bear population because of lack of suitable habitat and loss of traditional grizzly bear foods (*i.e.,* bison). Therefore, we did not need to determine if grizzly bears were in danger of extinction or likely to become so in these peripheral

areas (see *SPR Analysis for the GYE Grizzly Bear DPS*).

Determination

An assessment of the need for a species' protection under the Act is based on whether a species is in danger of extinction or likely to become so because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. As required by section 4(a)(1) of the Act, we conducted a review of the status of this species and assessed the five factors to evaluate whether the GYE grizzly bear DPS is endangered or threatened throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and foreseeable future threats faced by the species.

In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the exposure causes actual impacts to the species. If there is exposure to a factor and the species responds negatively, the factor may be a threat and we then attempt to determine how significant the threat is. If the threat is significant, it may drive, or contribute to, the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined by the Act. Alternatively, some threats may be significant enough to contribute to the risk of extinction but are adequately ameliorated through active conservation and management efforts so that the risk is low enough that it does not mean the species is in danger of extinction or likely to become so in the foreseeable future.

As demonstrated in our five-factor analysis, threats to this population and its habitat have been sufficiently minimized and the GYE grizzly bear DPS is a biologically recovered population. Multiple, independent lines of evidence support this interpretation. Counts of females with cubs-of-the-year have increased. Since at least 2001, the demographic recovery criterion that requires 16 of the 18 BMUs to be occupied with females with young has been met. The Recovery Plan target for a minimum population size of 500 animals inside the DMA to ensure genetic health has been met since at least 2007, using the conservative model-averaged Chao2 population estimator. Calculations of population trajectory derived from radio-monitored female bears showed an increasing population trend at a rate of 4 to 7 percent per year from 1983 through 2001 (Eberhardt *et al.* 1994, p. 362; Knight and Blanchard 1995, pp. 18–19; Schwartz *et al.* 2006b, p. 48), which had slowed to 0.3 to 2.2 percent from 2002 to 2011 (IGBST 2012, p. 34). The population trajectory that includes the most recent data is based on the Chao2 estimator and indicates no statistical trend (*i.e.,* relatively flat population trend) within the DMA for the period 2002 to 2014 (van Manen 2016a, *in litt.*).

Occupied grizzly bear range has more than doubled since 1975 (Basile 1982, pp. 3–10; Blanchard *et al.* 1992, p. 92; Schwartz *et al.* 2002, p. 203; Pyare *et al.* 2004, pp. 5–6; Schwartz *et al.* 2006a, pp. 64–66; Bjornlie *et al.* 2014a, p. 184). Independent female survival rates, the single most important cohort to population trajectory, are high and have remained unchanged for 3 decades (IGBST 2012, p. 33). In total, this population has increased from estimates ranging between 136 and 312 bears when listed in 1975 (Cowan *et al.* 1974, pp. 32, 36; Craighead *et al.* 1974, p. 16; McCullough 1981, p. 175), to an average population size between 2002–2014 of 674 using the model-averaged Chao2 population estimator.

Grizzly bears occupied 92 percent of suitable habitat within the DPS boundaries as of 2014 (Fortin-Noreus 2015, *in litt.*) and will likely occupy the remainder of the suitable habitat in the future. The GYE grizzly bear population currently has sufficient numbers and distribution of reproductive individuals to maintain its recovered status. The main threat of human-caused mortality has been addressed through carefully monitored and controlled total mortality limits established in the Grizzly Bear Recovery Plan Supplement (USFWS 2017, entire) and carried over into the 2016 Conservation Strategy (YES 2016a, pp. 33–53) and into State regulations as per tables 2 and 3 and discussed in *Factors B and C Combined,* above. These total mortality limits are calculated to ensure long-term population stability around the average population size for 2002–2014.

During our analysis, we did not identify any factors alone or in combination that reach a magnitude that threatens the continued existence of the species now or in the foreseeable future. Significant threats identified at the time of listing that could have resulted in the extirpation of the population have been eliminated or reduced since listing. We conclude that known impacts to the GYE grizzly bear population from the loss of secure habitat and development on public lands (*Factor A*); unregulated, excessive human-caused mortality (*Factors B and C Combined*); a lack of regulatory mechanisms to manage habitat and population (*Factor D*); and genetic isolation, changes to food resources, climate change, catastrophic events, or negative public attitudes (*Factor E*), do not rise to a level of significance, such that the population is in danger of extinction now or in the foreseeable future. Thus, based on our assessment of the best scientific and commercial information available, on our expectation that current management practices will continue into the foreseeable future—Federal regulations to maintain habitat protections as per *Factor A,* above, and State regulations that will regulate total mortality as per tables 2 and 3 and *Factors B and C Combined,* above—we, therefore, determine that the GYE grizzly bear DPS has recovered to the point at which protection under the Act is no longer required. The best scientific and commercial data available indicate that the GYE grizzly bear DPS is not endangered or threatened throughout all of its range.

Significant Portion of its Range Analysis

Background

Having determined that the GYE grizzly bear DPS is not in danger of extinction or likely to become so in the foreseeable future throughout all of its range, we next consider whether there are any significant portions of its range in which the GYE grizzly bear DPS is in danger of extinction or likely to become so. The phrase ''significant portion of its range'' (SPR) is not defined by the Act, and we have never addressed it in our regulations: (1) The outcome of a determination that a species is either in danger of extinction or likely to become so in the foreseeable future throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountain gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. Sept. 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's

prairie dog (73 FR 6660, February 5, 2008). The Service had asserted in both of these determinations that it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (*i.e.,* species, subspecies, or DPS), under the Act. Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that, once a determination is made that a species (*i.e.,* species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this rule, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing a species in its entirety; thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be in danger of extinction or likely to become so in the foreseeable future throughout all of its range; or a species may be in danger of extinction or likely to become so throughout a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Therefore, the consequence of finding that a species is in danger of extinction or likely to become so throughout a significant portion of its range is that the entire species will be listed as an endangered species or threatened species, respectively, and the Act's protections will be applied to all individuals of the species wherever found.

We conclude, for the purposes of this rule, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (*i.e.,* prior to the 2007 Department of the Interior Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this rule, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this rule, a portion of the range of a species is ''significant'' if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. *Resiliency* describes the characteristics of a species that allow it to recover from periodic disturbance. *Redundancy* (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. *Representation* (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitats is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain stressors, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one of these concepts.

For the purposes of this rule, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, *without that portion,* the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to stressors to the point that the overall species would be in danger of extinction or likely to become so in the foreseeable future (*i.e.,* would be ''endangered'' or ''threatened''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction or likely to become so throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' establishes a threshold that is relatively high. On the one hand, given that the outcome of finding a species to be in danger of extinction or likely to become so in an SPR would be listing all individuals of the species wherever found, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this rule carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions would be imposed or

resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''throughout a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be *currently* imperiled everywhere. Under the definition of ''significant'' used in this rule, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation we ask whether the species would be in danger of extinction or likely to become so everywhere without that portion, *i.e.,* if that portion were completely extirpated. In other words, the portion of the range need not be so important that even being in danger of extinction in that portion would be sufficient to cause the remainder of the range to be endangered; rather, the *complete extirpation* (in a hypothetical future) of the species in that portion would cause the remainder of the range to be in danger of extinction or likely to become so in the foreseeable future.

In implementing this interpretation, the first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we determine the species is an endangered species (or threatened species) and no SPR analysis will be required. If the species is neither in danger of extinction nor likely to become so throughout all of its range, we next determine whether the species is in danger of extinction or likely to become so throughout a significant portion of its range. If it is, we determine the species is an endangered species or threatened species, respectively; if it is not, we conclude that the species is neither an endangered species nor a threatened species.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant *and* threatened or endangered. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the stressors it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of identifying portions for further analysis is to examine whether there are threats that are geographically concentrated in some way. If the potential threats to the species are essentially uniform throughout its range, no portion is likely to be endangered or threatened and thus would not warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

SPR Analysis for the GYE Grizzly Bear DPS

Applying the process described above, we first evaluated the current range of the GYE grizzly bear DPS to determine if any area could be considered a significant portion of its 50,280 km^2 (19,413 mi^2) range (Bjornlie *et al.* 2014a, p. 184). The current range of the GYE grizzly bear DPS includes 44,624 km^2 (17,229 mi^2) inside the DMA and 5,656 km^2 (2,184 mi^2) outside the DMA. As mentioned above, one way to identify portions for further analyses is to identify portions that might be of biological or conservation importance, such as any natural, biological divisions within the current range that may, for example, provide population redundancy or have unique ecological, genetic, or other characteristics. Based on examination of the best available science (Schwartz *et al.* 2006b, entire; IGBST 2012, entire), we determined the GYE grizzly bear population is a single, contiguous population within the DPS boundaries and that there are no separate areas of the range that are significantly different from others or that are likely to be of greater biological or conservation importance than any other areas due to natural biological reasons alone. Therefore, there is not substantial information that logical, biological divisions exist within the GYE grizzly bear population's current range.

The Service has identified the PCA as a secure area for grizzly bears, with population and habitat condition maintained to ensure a recovered population is maintained and to allow bears into suitable habitat. This is likely to be significant (*i.e.,* if this area were hypothetically lost, the rest of the range would at that point be threatened or endangered) because it contains approximately 75 percent of females with cubs-of-the-year for most or part of the year (Schwartz *et al.* 2006a, pp. 64–66; Haroldson 2014a, *in litt.*). However, as noted above in our summary of factors affecting the species, threats to the species within this area have been ameliorated through restoration and active management as discussed in the factors above. Surveys indicate that the species has been maintained and is well-established, and remaining factors that may affect the species occur at low levels throughout this area. There is no substantial information indicating the species is likely to be threatened or endangered throughout this area, the PCA. Therefore, the PCA does not warrant further consideration to determine whether the species may be endangered or threatened in a significant portion of its range.

After determining there are no natural divisions delineating separate portions of the GYE grizzly bear population, or other important areas that warrant further consideration, we next examined whether any stressors are geographically concentrated in some way that would indicate the species could be in danger of extinction, or likely to become so, in that area. Through our review of potential threats, we identified greater mortality risk in the areas on the periphery of the population's current range. More grizzly bear mortality occurs toward the periphery of its range, as evidenced by lower population growth rates in these areas (Schwartz *et al.* 2006b, p. 58; IGBST 2012, p. 34) and higher likelihood of conflicts (Gunther *et al.* 2012, p. 50). These areas where greater mortality is likely to occur are outside the DMA boundaries (figure 1). We do not anticipate declines in relative population size or geographically concentrated stressors inside the DMA boundaries due to conservative population objectives, enforceable mortality limits, vast amounts of wilderness and roadless areas, and

additional habitat protections specifically in place for grizzly bears on public lands in nearly half of their current range (*i.e.,* the PCA). With these measures evaluated by a meticulous monitoring program, we are reasonably assured that grizzly bears inside the DMA boundaries will continue to flourish. Because it is also reasonable to expect that GYE grizzly bears may not be managed as conservatively outside the DMA boundaries where they could be exposed to more intensive hunting and management pressure, we considered these peripheral areas where known grizzly bear range extends outside the DMA boundaries to warrant further consideration to determine if they are a significant portion of this population's range.

Because we identified areas on the periphery of the current range as warranting further consideration due to the geographic concentration of mortality risk there, we then evaluated whether these areas are significant to the GYE grizzly bear population such that, without the members in that portion, the entire population would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range.

The core population inside the DMA is resilient, and its current range provides the necessary redundancy to offset loss of individual bears in peripheral areas. The areas that may experience higher mortality rates represent a very small proportion of the range, and an even smaller proportion of the total number of animals in the GYE grizzly bear population. Moreover, if bears in these peripheral areas were in fact lost, that loss would not significantly affect the long-term viability of the GYE grizzly bear population, much less cause the population in the remainder of its range to be in danger of extinction or likely to become so. Therefore, there is not substantial information indicating that the peripheral portions of the GYE grizzly bear population's range are significant to the rest of the population.

After careful examination of the GYE grizzly bear population in the context of our definition of ''significant portion of its range,'' we determined areas on the periphery of the range warranted further consideration because human-caused mortality risk is geographically concentrated there. After identifying these areas, we evaluated whether they were significant and determined they were not significant because, even without the grizzly bears in these areas, the GYE grizzly bear DPS would not be in danger of extinction, or likely to become so in the foreseeable future. These areas will likely never contribute meaningfully to the GYE grizzly bear population because of lack of suitable habitat and loss of traditional grizzly bear foods (*i.e.,* bison). Therefore, we did not need to determine if grizzly bears were in danger of extinction or likely to become so in these peripheral areas. We have carefully assessed the best scientific and commercial data available and determined that the GYE grizzly bear population is no longer in danger of extinction throughout all or a significant portion of its range, nor is it likely to become so in the foreseeable future. As a result of this determination, we hereby remove this population from the List of Endangered and Threatened Wildlife.

We are aware of the March 28, 2017, Arizona District Court ruling in *Center for Biological Diversity, et al.* v. *Sally Jewel, et al.,* which vacated and remanded the Service's 2014 Final SPR Policy (79 FR 37578, July 1, 2014). The district court found that our 2014 SPR Policy did not give sufficient independent meaning to the SPR phrase and thereby avoided the need to provide rangewide protections to a species based on threats in a portion of the species' range. The Service is currently considering appropriate next steps in light of the district court's decision. However, we have decided to finalize this action because our final determination on the recovered status of the GYE grizzly bear population does not hinge on the SPR analysis. As stated above, if grizzly bears in the periphery of the current range were in fact lost due to the geographic concentration of mortality risk, that loss would not appreciably reduce the long-term viability of the GYE grizzly bear population, much less cause the population in the remainder of its range to be in danger of extinction or likely to become so. In other words, under any definition of SPR it is clear that the GYE grizzly bear population is not in danger of extinction throughout all or a significant portion of its range, nor is it likely to become so in the future.

Effects of the Rule

This final rule revises 50 CFR 17.11(h) by establishing a DPS and removing the GYE grizzly bear DPS from the Federal List of Endangered and Threatened Wildlife. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to this DPS. Federal agencies would no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect the GYE grizzly bear population. However, actions within the DPS would still be managed by State, Tribal, and Federal laws, regulations, policies, and management plans ensuring enforcement of the 2016 Conservation Strategy. Delisting the GYE grizzly bear DPS is expected to have positive effects in terms of management flexibility to the States and local governments. The full protections of the Act, including section 4(d) (50 CFR 17.40), would still continue to apply to grizzly bear populations in other portions of the lower-48 States outside the GYE grizzly bear DPS' boundaries. Those grizzly bears outside the GYE DPS will remain fully protected by the Act.

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us to implement a system, in cooperation with the States, to monitor for at least 5 years all delisted and recovered species. The primary purpose of this requirement is to ensure that the recovered species does not deteriorate, and if an unanticipated decline is detected, to take measures to halt the decline to avoid re-listing. If data indicate that protective status under the Act should be reinstated, we will initiate listing procedures, including, if appropriate, emergency listing.

For the GYE grizzly bear population, the 2016 Conservation Strategy serves as the post-delisting monitoring plan. The 2016 Conservation Strategy will remain in effect for the foreseeable future, beyond the 5-year monitoring period required by the Act due to their low resiliency to excessive human-caused mortality and the manageable nature of this threat. These management actions are detailed in the 2016 Conservation Strategy and will be evaluated by the management agencies every 5 years, allowing for public comment should updates to the Conservation Strategy be made in the future.

Monitoring

To ensure the long-term conservation of grizzly bear habitat and continued recovery of the GYE grizzly bear population, several monitoring programs and protocols have been developed and integrated into land management agency planning documents. The 2016 Conservation Strategy and appended State grizzly bear management plans satisfy the requirements for having a post-delisting monitoring plan for the GYE grizzly bear population. Monitoring programs and a coordinated approach to management would continue for the foreseeable future. Monitoring programs will focus on assessing whether demographic and

habitat standards described in the 2016 Conservation Strategy are being achieved and maintained.

Within the PCA, the IGBST will continue to monitor habitat standards and adherence to the 1998 baseline. The IGBST will report on levels of secure habitat, developed sites, and livestock allotments annually, and these will not be allowed to deviate from 1998 baseline values unless changes were to be beneficial to grizzly bears (USDA FS 2006b, entire; YNP 2014b, p. 18). The IGBST, with participation from YNP, the USFS, and State and Tribal wildlife agencies, also will continue to monitor the abundance and distribution of common grizzly bear foods. This system allows managers some degree of predictive power to anticipate and avoid grizzly bear-human conflicts related to a shortage of one or more foods in a given season.

Within the DMA, the IGBST will continue to document population trends, current distribution, survival and birth rates, and the presence of alleles from grizzly bear populations outside the GYE grizzly bear DPS boundaries to document gene flow into the population. Throughout the DPS boundaries, locations of grizzly bear mortalities on private lands will be provided to the IGBST for incorporation into their annual report. To examine reproductive rates, survival rates, causes of death, and overall population trends, the IGBST will radio-collar and monitor a minimum of 25 adult female grizzly bears every year and a similar representative sample of adult males. The objective will be to maintain a radio-marked sample of bears that are spatially distributed throughout the ecosystem so they provide a representative sample of the entire population inside the DMA. Mortalities throughout the GYE DPS will be monitored and reported annually and evaluated in accordance with the DMA total mortality limits and population objectives in table 3.

Outside of the PCA, the GYE National Forests will monitor agreed-upon habitat parameters in suitable habitat and will calculate secure habitat values outside of the PCA every 2 years and submit these data for inclusion in the IGBST's annual report (USDA FS 2006b, p. 6). The GYE National Forests also will monitor and evaluate livestock allotments for recurring conflicts with grizzly bears in suitable habitat outside the PCA (USDA FS 2006b, p. 6). The Greater Yellowstone Whitebark Pine Monitoring Group will continue to monitor whitebark pine occurrence, productivity, and health both inside and outside the PCA (USDA FS 2006b, p. 7). Members of the IGBST will monitor grizzly bear vital rates and population parameters within the entire DMA. Finally, State wildlife agencies will provide known mortality information to the IGBST, which will annually summarize these data with respect to location, type, date of incident, and the sex and age of the bear for the entire DPS area.

In the 2007 final rule (72 FR 14866, March 29, 2007), we reported habitat quality and effectiveness values for 1998 using the Cumulative Effects Model and associated 1998 habitat data (USFWS 2007*c,* appendix F). Since 1998, the value of the Cumulative Effects Model has been questioned (Boyce *et al.* 2001, p. 32). Specifically, the validity of all the coefficients cannot be verified or ground-truthed, calling into question all of the model outputs. Without scientific and statistical defensibility, the Cumulative Effects Model will not produce credible results and it cannot be used (Boyce *et al.* 2001, p. 32; Borkowski 2006, pp. 85–87). While the Cumulative Effects Model provided an index of relative change in habitat quality over time, it was never able to predict grizzly bear habitat use or preference or relate habitat to changes in population parameters. Because we no longer consider the Cumulative Effects Model to represent the best available science, we are no longer relying on or reporting measures of habitat quality or effectiveness using it. Instead, the IGBST will assess and report human-caused changes to grizzly bear habitat through maintenance of the 1998 baseline values for developed sites, grazing allotments, and secure habitat (YES 2016b, appendix E).

While the inverse relationship between whitebark pine seed production and grizzly bear conflicts in the GYE has been documented (Mattson *et al.* 1992, p. 436; Gunther *et al.* 1997, p. 38; Gunther *et al.* 2004, pp. 13–14), there are no data relating other foods such as spring ungulate carcasses, army cutworm moths, and cutthroat trout to the number of grizzly bear-human conflicts. Additionally, Schwartz *et al.* (2010, p. 662) found no relationship between the spatial distribution of whitebark pine, cutthroat trout, army cutworm moths, or ungulates and grizzly bear survival. Therefore, while it is important to continue to monitor food abundance, there is no scientific evidence that habitat quality is a limiting factor for grizzly bear survival in the GYE. The IGBST will continue coordinating with the National Forests and National Parks within the PCA to monitor food abundance but will focus management recommendations on regulating the risk of human-caused mortality through the 1998 baseline (*i.e.,* factors the agencies have the authority and ability to regulate). Private land development and the numbers, causes, and spatial distribution of human-bear conflicts will continue to be monitored and reported annually, because this scenario is where habitat quality intersects with grizzly bear mortality risk.

To address the possible ''lag effect'' associated with slow habitat degradation taking a decade or more to translate into detectable changes in population size (see Doak 1995), the IGBST will monitor a suite of indices simultaneously to provide a highly sensitive system to monitor the health of the population and its habitat and to provide a sound scientific basis to respond to any changes or needs with adaptive management actions (Holling 1978, pp. 11–16). This ''lag effect'' is a concern only if the sole method to detect changes in habitat is monitoring changes in total population size (see Doak 1995, p. 1376). The monitoring systems in the 2016 Conservation Strategy (YES 2016a, pp. 33–85) are far more detailed and sophisticated and would detect changes in vital rates in response to habitat changes sooner than the system described by Doak (1995, pp. 1371–1372). The IGBST will be monitoring a suite of vital rates including survival of radio-collared bears, mortality of all bears, reproductive success, litter size, litter interval, number of females with cubs-of-the-year, distribution of females with young, and overall population trajectory, in addition to the physical condition of bears by monitoring body mass and body fat levels of each bear handled. Because of the scope of monitoring, we feel confident that we will be able to detect the consequences of significant changes in habitat within a reasonable timeframe that would allow for appropriate management response.

Monitoring systems in the 2016 Conservation Strategy allow for adaptive management (Holling 1978, pp. 11–16) as environmental issues change. The agencies have committed in the 2016 Conservation Strategy to be responsive to the needs of the grizzly bear through adaptive management (Holling 1978, pp. 11–16) actions based on the results of detailed annual population and habitat monitoring. These monitoring efforts would reflect the best scientific and commercial data and any new information that has become available since the delisting determination. The entire process would be dynamic so that when new science becomes available it

will be incorporated into the management planning and monitoring systems outlined in the 2016 Conservation Strategy (YES 2016a, pp. 33–91). The results of this extensive monitoring would allow wildlife and land managers to identify and address potential threats preemptively, allowing those managers to ensure that the GYE grizzly bear population remains a recovered population.

Triggers for a Biology and Monitoring Review by the IGBST

The YGCC will use the IGBST's monitoring results and annual reports to determine if the population and habitat standards are being adhered to. The States, Tribes, and National Parks will use the IGBST's annually produced model-averaged Chao2 population estimates to set and establish total mortality limits within the DMA as per tables 2 and 3. The 2016 Conservation Strategy signatories have agreed that if there are deviations from certain population or habitat standards, the IGBST will conduct a Biology and Monitoring Review as described under *Factors B and C Combined,* above. A Biology and Monitoring Review would be initiated if any of the following scenarios occur (as further described under *Factors B and C Combined,* above): (1) Exceeding the total mortality limit for independent females for 3 consecutive years; (2) exceeding the total mortality limits for independent males for 3 consecutive years; (3) exceeding the total mortality limit for dependent young for 3 consecutive years; (4) failure to meet the distribution criterion requiring sightings of females with young in at least 16 of 18 BMUs in 3 consecutive years; (5) failure to meet the model-averaged Chao2 estimate of 48 females with cubs-of-the-year for any 3 consecutive years.

In addition to the scenarios described under *Factors B and C Combined,* a Biology and Monitoring Review by the IGBST would be initiated if there were a failure to meet any of the habitat standards described in the 2016 Conservation Strategy pertaining to levels of secure habitat, developed sites, and livestock allotments. These IGBST reviews were established to detect deviations that may occur due to normal variability or chance events and do not necessarily mean the GYE grizzly bear's status is deteriorating. As such, they are more easily activated than those that trigger a Service status review under the Act. These triggers could indicate the need to adjust management approaches and are intended to provide the YGCC with ample time to respond with management actions before involving the Service. A Biology and Monitoring Review would be completed within 6 months of the request by the YGCC, and the resulting written report would be presented to the YGCC and made available to the public.

An IGBST Biology and Monitoring Review examines habitat management, population management, or monitoring efforts of participating agencies with an objective of identifying the source or cause of failing to meet a habitat or demographic goal. This review also will provide management recommendations to correct any such deviations. A Biology and Monitoring Review could occur if funding becomes inadequate to the implementation of the 2016 Conservation Strategy to such an extent that it compromised the recovered status of the GYE grizzly bear population. If the review is triggered by failure to meet a population goal, the review would involve a comprehensive review of vital rates including survival rates, litter size, litter interval, grizzly bear-human conflicts, and mortalities. The IGBST will attempt to identify the reason behind any variation in vital rates such as habitat conditions, poaching, excessive roadkill, etc., and determine if these compromise the recovered status of the population. Similarly, if the review was triggered by failure to meet a habitat standard, the review would examine what caused the failure, whether this situation requires that the measures of the Act are necessary to ensure the recovered status of the population, and what actions may be taken to correct the problem. The IGBST would complete this review and release it to the public within 6 months of initiation and make it available to the YGCC and the public.

The YGCC responds to a Biology and Monitoring Review with actions to address deviations from habitat standards or, if the desired population and habitat standards specified in the 2016 Conservation Strategy cannot be met in the opinion of the YGCC, the YGCC could recommend that the Service consider re-listing of the GYE grizzly bear DPS (YES 2016a, pp. 96–103). Because the YGCC possesses substantial information about the population's status, the Service would respond by conducting a status review to determine if re-listing is warranted.

The Service can also initiate a status review independent of the IGBST or the YGCC should the total mortality limits be exceeded by a significant margin or routinely violated or if substantial management changes occur significant enough to raise concerns about population-level impacts. Emergency re-listing of the population is an option we can and will use, if necessary, in accordance with section 4(g)(2) of the Act, to prevent a significant risk to the well-being of the grizzly bears (16 U.S.C. 1533(g)). Such an emergency re-listing would be effective the day the rule is published in the **Federal Register** and would be effective for 240 days. During this time, we would conduct our normal notice-and-comment rulemaking regarding the listing of the species based on the five factors of section 4(a)(1) of the Act to take effect when the 240-day limit on the emergency re-listing expires.

Triggers for a Service Status Review

Upon delisting of the GYE grizzly bear population, we will use the information in IGBST annual reports and adherence to total mortality limits as per tables 2 and 3 to determine if a formal status review is necessary. Because we anticipate that the YGCC and IGBST are fully committed to maintaining GYE grizzly bear population management and habitat management through implementation of the 2016 Conservation Strategy and State and Federal management plans, and to correct any problems through the process established in the 2016 Conservation Strategy and described in the preceding section, we created a threshold for criteria that would trigger a formal Service status review that is higher than that for a Biology and Monitoring Review. Specifically, any of the following scenarios would result in a formal status review by the Service:

(1) If there are any changes in Federal, State, or Tribal laws, rules, regulations, or management plans that depart significantly from the specifics of population or habitat management detailed in this final rule or the 2016 Conservation Strategy that would significantly increase the threat to the GYE grizzly bear population. The Service will promptly conduct such an evaluation of any change in a State or Federal agency's regulatory mechanisms to determine if such a change represents a threat to the GYE grizzly bear population. As the Service has done for the Rocky Mountain DPS of gray wolf, such an evaluation will be documented for the record and acted upon if necessary.

(2) A total population estimate is less than 500 inside the DMA in any year using the model-averaged Chao2 population estimator, or counts of females with cubs-of-the-year fall below 48 for 3 consecutive years.

(3) If fewer than 16 of 18 bear management units are occupied by females with young for 3 consecutive 6-year sums of observations.

(4) If the Service determines a petition to re-list from an individual or organization is substantial.

In addition to these four criteria for a status review, the Service may conduct a status review at any time that the best scientific information indicates a review may be necessary or if population and mortality targets in the 2016 Conservation Strategy are consistently not met. Upon completion of a formal status review, a notice of availability would be published in the **Federal Register**, and the review would be available at *http://www.fws.gov/mountain-prairie/es/grizzlyBear.php.* If a status review recommends re-listing the GYE grizzly bear DPS, a proposed listing rule would be published in the **Federal Register**, which is open to public comment and subject to peer review.

Status reviews and re-listing decisions would be based on the best available scientific and commercial data available. If a status review is triggered, the Service would evaluate the status of the GYE grizzly bear population to determine if re-listing is warranted. We would make prompt use of the Act's emergency listing provisions if necessary to prevent a significant risk to the well-being of the GYE grizzly bear population. We have the authority to emergency re-list at any time, and a completed status review is not necessary to exercise this emergency re-listing authority.

Required Determinations

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the NEPA of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Paperwork Reduction Act

This rule does not contain any new collections of information other than those already approved under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The 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.

Executive Order 13211

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. As this rule is not expected to significantly affect energy supplies, distribution, or use, this action is not a significant energy action and no Statement of Energy Effects is required.

Government-to-Government Relationships With Tribes

In accordance with the President's memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951), E.O. 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

Beginning in April 2014, the Service sent consultation invitation letters via registered mail to the four Tribes having treaty interests in the proposed GYE grizzly bear delisting area: the Northern Arapaho, Eastern Shoshone, Northwestern Band of the Shoshone Nation, and Shoshone-Bannock Tribes. Over the next year the Service was made aware of many more Tribes having an interest in the GYE grizzly bear and expanded our efforts in explaining the status of the bear and offering government-to-government consultation to Tribes.

On February 17, 2015, the Service sent letters offering government-to-government consultation to 26 Tribes. On June 15, 2015, the Service sent out a second round of letters to 48 tribes, offering another opportunity for consultation, followed by personal phone calls or emails from Service leadership to the 48 tribes, personally inviting them to engage in government-to-government consultation. On August 13, 2015, the Service met with the Rocky Mountain Tribal Leaders Council in Billings, Montana and invited tribal representative to engage in consultation concerning the GYE grizzly bear.

On October 29, 2015, the Service sent letters to 53 tribes, which included all Tribes, Tribal Councils, and First Nations in Canada that have contacted the Service regarding the GYE grizzly bear population. The letters invited all Federal Tribes to engage in government-to-government consultation. In addition, the letter invited Tribes to participate in an informational webinar and conference call held on November 13, 2015.

On March 3, 2016, the Service announced its proposal to delist grizzly bears in the GYE. The announcement was disseminated to all Tribes west of the Mississippi River with Tribes being notified by both email and hard copy mail. In addition, the Service announced two consultation meeting opportunities in the **Federal Register** and in the Tribal leader letters at the same time the proposed rule published. The two meetings were hosted in Bozeman, Montana and in Rapid City, South Dakota.

On March 10, 2016, the Service hosted a tribal conference call to provide an overview of the proposed delisting and discuss any questions or concerns. It was not considered government-to-government consultation. The announcement for this call was included in the March, 3rd notifications sent to Tribes.

To date, the Service has conducted ten Tribal consultations with the following Tribes: June 10, 2015: Confederated Salish and Kootenai Tribes; June 18, 2015: Blackfeet Nation Wildlife Committee; July 21, 2015: Northern Arapahoe Tribal Council; July 21, 2015: Eastern Shoshone Tribal Council; July 30, 2015: Shoshone Bannock Tribal Council; April 28, 2016: Bozeman Montana (Tribes Present at meeting: Shoshone Bannock Tribes, Northern Cheyenne Tribe, Eastern Shoshone Tribe, Northwest Band of the Shoshone); May 5, 2016: Rapid City, South Dakota (Northern Arapaho, Rosebud Sioux); November 2, 2016: Eastern Shoshone Tribe; November 16, 2016: Shoshone Bannock Tribe; April 07, 2017: Northern Cheyenne Tribal Council. Government-to-Government consultation is not open to the public or media. This process involves consultation with Tribal members speaking on behalf of their Tribe and as a representative of their Tribe (see **FOR FURTHER INFORMATION CONTACT** above, for more information).

References Cited

A complete list of all references cited in this final rule is available at *http://www.regulations.gov* at Docket No. FWS–R6–ES–2016–0042, or is available upon request from the Grizzly Bear Recovery Coordinator (see **ADDRESSES**).

Glossary

1998 baseline: The 1998 baseline represents the best available habitat measures representing ground conditions inside the

Primary Conservation Area (PCA) as of 1998. Habitat standards identified in the 2016 Conservation Strategy pertain to secure habitat, developed sites, and livestock grazing allotments. The standards demand that all three of these habitat parameters are to be maintained at or improved upon conditions that existed in 1998. The 1998 baseline represents the best estimate of what was known to be on the ground at that time and establishes a benchmark against which future improvements and/or impacts can be assessed. It also provides a clear standard for agency managers to follow when considering project-effect analysis.

Chao2 estimator: A bias-corrected estimator of the total number of female grizzly bears with cubs-of-the-year, derived from the frequency of single sightings or double sightings of unique females with cubs-of-the-year (Keating *et al.* 2002; Cherry *et al.* 2007) as identified based on a rule set by Knight *et al.* (1995).

Cubs: Any use of the word cubs is synonymous to cubs-of-the-year.

Demographic monitoring area (DMA): The area of suitable habitat plus the potential sink areas within which the GYE grizzly bear population is annually surveyed and estimated and within which the total mortality limits apply. The DMA is 49,928 km^2 (19,279 mi^2). See figure 1 for a map showing the DMA.

Dependent young: Young grizzly bears less than 2 years old. Dependent young are with their mothers and are dependent upon them for survival.

Discretionary mortality: Mortalities that are the result of hunting or management removals.

Distinct population segment (DPS): The Service defined a DPS in the DPS policy (61 FR 4722, February 7, 1996) that considers two factors to determine whether the population segment is a valid DPS: (1) Discreteness of the population segment in relation to the remainder of the taxon to which it belongs; and (2) the significance of the population segment to the taxon to which it belongs. If a population meets both tests, it is a DPS, and the Service then evaluates the population segment's conservation status according to the standards in section 4 of the Act for listing, delisting, or reclassification.

Greater Yellowstone Ecosystem (GYE): YNP and GTNP form the core of the GYE, which includes portions of three States: Wyoming, Montana, and Idaho. At more than 90,000 km^2 (34,750 mi^2), it is one of the largest nearly intact temperate-zone ecosystems on Earth.

Illegal kills: Illegal human-caused mortality, including but not limited to, vandal killings, poaching, and mistaken identity kills.

Independent females: Grizzly bear females 2 years old or older.

Independent males: Grizzly bear males 2 years old or older.

Interagency Grizzly Bear Study Team (IGBST): The Interagency Grizzly Bear Study Team (IGBST) is an interdisciplinary group of scientists and biologists responsible for long-term monitoring and research efforts on grizzly bears in the GYE. The main objectives of the team are to: (1) Monitor the status and trend of the grizzly bear population in the GYE; and (2) determine patterns of habitat use by bears and the relationship of land management activities to the welfare of the bear population. The IGBST is led by the USGS. IGBST members are representatives from the USGS, NPS, Service, USFS, the Eastern Shoshone and Northern Arapaho Tribal Fish and Game Department, and the States of Idaho, Montana, and Wyoming.

Model-averaged Chao2 estimator: The method to estimate the total number of female grizzly bears with cubs-of-the-year based on a statistical weighting of linear and quadratic regression models fitted to data since 1983 to smooth annual variations in the time series, and using endpoint in the time series as the estimate for the current year.

Model-averaged Chao2 population estimator: The method to estimate the total population size derived from the model-averaged Chao2 estimate of females with cubs-of-the-year.

Primary Conservation Area (PCA): The name of the Recovery Zone area post-delisting. The habitat-based recovery criteria apply within the PCA.

Recovery Zone: The area defined in the 1993 Grizzly Bear Recovery Plan within which the recovery efforts would be focused in the GYE. The Recovery Zone is not designed to contain all grizzly bears.

Significant portion of its range (SPR): The Service defines a portion of the range of a species as ''significant'' if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range.

Suitable habitat: We define suitable habitat for grizzly bears as areas having three characteristics: (1) Being of adequate habitat quality and quantity to support grizzly bear reproduction and survival; (2) being contiguous with the current distribution of GYE grizzly bears such that natural recolonization is possible; and (3) having low mortality risk as indicated through reasonable and manageable levels of grizzly bear mortality. Suitable habitat is made up of the Middle Rockies ecoregion, within which the GYE is contained. This area meets grizzly bear biological needs providing food, seasonal foraging opportunities, cover, and denning areas. See the *Suitable Habitat* section of this final rule for a more complete explanation.

Total mortality: Documented known and probable grizzly bear mortalities from all causes including but not limited to: Management removals, illegal kills, mistaken identity kills, self-defense kills, vehicle kills, natural mortalities, undetermined-cause mortalities, grizzly bear hunting, and a statistical estimate of the number of unknown/unreported mortalities.

Transition probability: The probability of a transition for an adult female (greater than 3 years old) among reproductive states. The possible reproductive states are: no young, with cubs-of-the-year, with yearlings, or with 2-year-olds. Ten potential reproductive transitions are biologically feasible.

Yellowstone Grizzly Bear Coordinating Committee (YGCC): The committee of State, Federal, Tribal, and county agencies charged with implementing the 2016 Conservation Strategy post delisting. They will coordinate management and promote the exchange of information about the GYE grizzly bear population. Members include: YNP and GTNP; five National Forests: Beaverhead-Deerlodge, Bridger-Teton, Caribou-Targhee, Custer Gallatin, and Shoshone; one BLM representative; the Biological Resources Division of the USGS; one representative each from Idaho, Montana, and Wyoming; and one representative from each Native American Tribe with sovereign powers over reservation lands within the ecosystem.

Authors

The primary authors of this final rule are staff members of the Service's Grizzly Bear Recovery Office (see **FOR FURTHER INFORMATION CONTACT**)

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we hereby amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by revising the first entry for ''Bear, grizzly'' under ''Mammals'' in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
Mammals				
*	*	* * * * * *	*	
Bear, grizzly	*Ursus arctos horribilis.*	U.S.A., conterminous (lower 48) States, except: (1) Where listed as an experimental population; and (2) that portion of Idaho that is east of Interstate Highway 15 and north of U.S. Highway 30; that portion of Montana that is east of Interstate Highway 15 and south of Interstate Highway 90; that portion of Wyoming south of Interstate Highway 90, west of Interstate Highway 25, Wyoming State Highway 220, and U.S. Highway 287 south of Three Forks (at the 220 and 287 intersection), and north of Interstate Highway 80 and U.S. Highway 30.	T	32 FR 4001, 3/11/1967; 35 FR 16047, 10/13/1970; 40 FR 31734, 7/28/1975; 72 FR 14866, 3/29/2007; 82 FR [Insert **Federal Register** page where the document begins], 6/30/2017; 50 CFR 17.40(b).[4d]
*	*	* * * * * *	*	

Dated: June 1, 2017.

James W. Kurth,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2017–13160 Filed 6–29–17; 8:45 am]

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FEDERAL REGISTER

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Part IV

Environmental Protection Agency

40 CFR Part 52
Air Plan Approval; Illinois; Revised Format for Materials Incorporated by Reference; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2016–0599; FRL–9963–76–Region 5]

Air Plan Approval; Illinois; Revised Format for Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: The Environmental Protection Agency (EPA) is revising the format for materials that are made part of the Illinois State Implementation Plan (SIP) through the process of incorporation by reference (IBR). The regulations and materials affected by this format change have all been previously submitted by Illinois and approved by EPA as part of the SIP.

DATES: This action is effective June 30, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2016–0599. SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604 and the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Christos Panos, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR 18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8328, *panos.christos@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us'' or ''our'' is used, it is intended to refer to EPA. Information is organized as follows:

Table of Contents

I. Background

A. Description of a SIP

Each state has a SIP containing, among other things, the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring networks, attainment demonstrations, and enforcement mechanisms.

B. How EPA Enforces SIPs

Each state must formally adopt the control measures and strategies to attain and maintain the NAAQS after the public has had an opportunity to comment on them. The states then submit them to EPA as SIP revision requests upon which EPA must formally act. EPA evaluates these submissions to determine whether they meet CAA requirements. If and when these control measures and strategies are approved by EPA, after notice and comment rulemaking, EPA uses the IBR process to make them part of the Federally approved SIP. IBR is a method of incorporating material into EPA regulations in the CFR by referencing the original document(s) without publishing the full text of the material. In this case, the SIP rules are identified in part 52 (Approval and Promulgation of Implementation Plans), title 40 of the Code of Federal Regulations (40 CFR part 52). These rules are approved by EPA with a specific effective date, but are not reproduced in their entirety in 40 CFR part 52. This format allows both EPA and the public to identify which regulations are contained in a given SIP and to help determine whether the state is enforcing those regulations. This format also assists EPA and the public in taking enforcement action, should a state not enforce its SIP-approved regulations.

C. How the State and EPA Update the SIP

The SIP is periodically revised as necessary to address the unique air pollution problems in the state. Therefore, EPA must periodically take action on state SIP submissions containing new and/or revised regulations and other materials; if approved, they become part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the formatting procedures of 40 CFR part 52 for incorporating by reference Federally approved SIP revisions. These procedures include: (1) A revised SIP document for each state that would use the IBR process under the provisions of title 1 CFR part 51; (2) a revised mechanism for announcing EPA approval of revisions to an applicable SIP and updating both the document that has gone through the IBR process and the CFR; and (3) a revised format of the ''Identification of plan'' sections for each applicable subpart in 40 CFR part 52 to reflect these revised IBR procedures. The description of the revised SIP document, IBR procedures, and ''Identification of plan'' format are discussed in further detail in the May 22, 1997 **Federal Register** document.

D. How EPA Compiles the SIPs

The Federally-approved regulations, source-specific requirements, and nonregulatory provisions (entirely or portions of) submitted by each state agency have been compiled by EPA into a ''SIP compilation.'' The SIP compilation contains the updated regulations, source-specific requirements, and nonregulatory provisions approved by EPA through previous rulemaking actions in the **Federal Register**.

E. How EPA Organizes the SIP Compilation

Each SIP compilation contains three parts. Part one contains the regulations, part two contains the source-specific requirements, and part three contains nonregulatory provisions. Each state's SIP compilation contains a table for each of the three parts that identifies each SIP-approved regulation, source-specific requirement, and nonregulatory provision. In this action, EPA is publishing the SIP compilation tables that summarize the applicable SIP requirements for Illinois and that will be codified at 40 CFR 52.720. The effective dates in the table indicate the date of the most recent revision to an approved regulation. EPA Regional Offices have the primary responsibility for updating the state SIP compilations and ensuring their accuracy.

F. Where You Can Find a Copy of the SIP Compilation

EPA Region 5 has developed and will maintain the SIP compilation for Illinois. A copy of the full text of Illinois's regulatory and source-specific SIP compilation will also be maintained at NARA.

G. The Format of the New Identification of Plan Section

In order to better serve the public, EPA revised the organization of the section titled ''Identification of plan'' at 40 CFR 52.720 and included additional information to clarify the enforceable elements of the SIP. The revised format does not affect Federal enforceability of the SIP and is consistent with the requirements of Section 110(h)(1) of the CAA concerning comprehensive SIP publication.

The revised Identification of plan section contains five subsections: (a) Purpose and scope, (b) Incorporation by reference, (c) EPA approved regulations, (d) EPA approved source specific requirements, and (e) EPA approved nonregulatory and quasi-regulatory provisions.

H. When a SIP Revision Becomes Federally Enforceable

All new requirements and revisions to the applicable SIP become Federally enforceable as of the effective date of the revisions to paragraphs (c), (d), or (e) of the applicable Identification of plan section found in each subpart of 40 CFR part 52.

I. The Historical Record of SIP Revision Approvals

To facilitate enforcement of previously approved SIP provisions and provide a smooth transition to the new SIP processing system, EPA will retain the original Identification of plan section, previously appearing in the CFR as the first or second section of part 52 for each state subpart. The original Identification of plan section will be moved to Section 52.750 of part 52 for Illinois. After an initial two-year period, EPA will review its experience with the new SIP processing system and decide whether to retain the original Identification of plan section for some further period.

II. What EPA Is Doing in This Action

We are revising the format of 40 CFR part 52 ''Identification of plan'' section for Illinois regarding incorporation by reference, by adding Section 52.720(c)(d) and (e), to be consistent with the format described above and in 62 FR 27968 (May 22, 1997). We are adding Section 52.720(b)(1) to further clarify that all SIP revisions listed in Section 52.720(c) and (d), regardless of inclusion in the most recent ''update to the SIP compilation,'' are Federally enforceable under sections 110 and 113 of the Clean Air Act (CAA) as of the effective date of the final rulemaking in which EPA approved the SIP revision. We are adding Section 52.720(b)(2) to certify that the materials provided by EPA at the addresses in paragraph (b)(3) are an exact duplicate of the official state rules/regulations. We are adding Section 52.720(b)(3) to update address and contact information. Additionally, we are removing sections 52.729 ''Control strategy: Carbon monoxide'', 52.745 ''Section 110(a)(2) infrastructure requirements'' and 52.746 ''Control strategy: Lead (Pb)'' because the information within those sections is being incorporated into the tables at Section 52.720 and is, therefore, no longer necessary.

This action constitutes a recordkeeping and organizational exercise to ensure that all revisions to the state programs that have occurred are accurately reflected in 40 CFR part 52. State SIP revisions are controlled by EPA regulations at 40 CFR part 51.

EPA has determined that this action falls under the ''good cause'' exemption in sections 553(b)(3)(B) and 553(d)(3) of the Administrative Procedures Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and allows an agency to make a rule effective immediately, thereby avoiding the 30-day delayed effective date otherwise provided for in the APA. This action simply reformats and codifies provisions which are already in effect as a matter of law in Federal and approved state programs. Under section 553(b)(3)(B) of the APA, an agency may find good cause where notice and public procedure are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is unnecessary for this action because EPA is reformatting and codifying existing law. Immediate notice in the CFR benefits the public by removing outdated citations and making the IBR format clearer and more user-friendly.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Illinois Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute as indicated in the **SUPPLEMENTARY INFORMATION** section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it 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). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. This rule does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996).

EPA has complied with Executive Order 12630 (63 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rules is discussed in previous actions taken on the State's rules.

B. Submission to Congress and the Comptroller General

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This action simply codifies provisions which are already in effect as a matter of law in Federal and approved state programs. 5 U.S.C. 802(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective of June 30, 2017. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. The changes in format to the ''Identification of plan'' section for Illinois are not a 'major rule' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

EPA has also determined that the provisions of section 307(b)(1) of the Clean Air Act pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the Illinois SIP compilations had previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA sees no need in this action to reopen the 60-day period for filing such petitions for judicial review for these ''Identification of plan'' reorganization actions for Illinois.

List of Subjects in 40 CFR Part 52

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

Dated: June 5, 2017.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

Part 52 of chapter I, title 40 of the Code of Federal Regulations, is amended as follows:

PART 52—APROVAL AND PROMULGATION OF IMPLEMENTION PLANS

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

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

Subpart O—Illinois

§ 52.720 [Redesignated as § 52.750 and amended]

■ 2. Section 52.720 is redesignated as § 52.750 and the section heading and paragraph (a) are revised to read as follows:

§ 52.750 Original identification of plan section.

(a) This section identified the original ''Air Quality Implementation Plan for the State of Illinois'' and all revisions submitted by Illinois that were Federally-approved prior to June 1, 2017.

* * * * *

■ 3. A new § 52.720 is added to read as follows:

§ 52.720 Identification of plan.

(a) *Purpose and scope.* This section sets forth the applicable State implementation plan for the State of Illinois under section 110 of the Clean Air Act, 42 U.S.C. 7401–7671q and 40 CFR part 51 to meet national ambient air quality standards.

(b) *Incorporation by reference.*

(1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to December 31, 2016, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Entries in paragraphs (c) and (d) of this section with the EPA approval dates after December 31, 2016, have been approved by EPA for inclusion in the State implementation plan and for incorporation by reference into the plan as it is contained in this section, and will be considered by the Director of the Federal Register for approval in the next update to the SIP compilation.

(2) EPA Region 5 certifies that the materials provided by EPA at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated state rules/regulations which have been approved as part of the state implementation plan as of the dates referenced in paragraph (b)(1).

(3) Copies of the materials incorporated by reference into the SIP may be inspected at the Region 5 EPA Office at 77 West Jackson Boulevard, Chicago, IL 60604. To obtain the material, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble. You may also inspect the material with an EPA approval date prior to June 1, 2017, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) *EPA approved regulations.*

EPA-APPROVED ILLINOIS REGULATIONS AND STATUTES

Illinois citation	Title/subject	State effective date	EPA approval date	Comments
Title 35 of the Illinois Administrative Code				
Subtitle A: General Provisions				
Chapter I: Pollution Control Board				
Part 106: Procedural Regulations				
Subpart E: Alternative Opacity Procedures				
106.501	Scope and Applicability	07/13/88	12/29/92, 57 FR 61834.	
106.502	Joint or Single Petition	07/13/88	12/29/92, 57 FR 61834.	
106.503	Request to Agency to Join as Co-Petitioner	07/13/88	12/29/92, 57 FR 61834.	
106.504	Contents of Petition	07/13/88	12/29/92, 57 FR 61834.	
106.505	Response and Reply	07/13/88	12/29/92, 57 FR 61834.	
106.506	Notice and Conduct of Hearing	06/05/90	12/29/92, 57 FR 61834.	
106.507	Opinions and Orders	07/13/88	12/29/92, 57 FR 61834.	
Subpart J: Culpability Determinations				
106.930	Applicability	07/11/94	07/13/95, 60 FR 36060.	
106.931	Petition for Review	07/11/94	07/13/95, 60 FR 36060.	
106.932	Response and Reply	07/11/94	07/13/95, 60 FR 36060.	
106.933	Notice and Hearing	07/11/94	07/13/95, 60 FR 36060.	
106.934	Opinion and Order	07/11/94	07/13/95, 60 FR 36060.	
Subtitle B: Air Pollution				
Chapter I: Pollution Control Board				
Subchapter a: Permits and General Provisions				
Part 201: Permits and General Provisions				
Subpart A: Definitions				
201.102	Definitions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 101.
Subpart B: General Provisions				
201.121	Existence of Permit No Defense	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(h).
201.122	Proof of Emissions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 108.
201.123	Burden of Persuasion Regarding Exceptions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 111.
201.124	Annual Report	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 112.
201.125	Severability	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 113.
201.126	Repealer	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 114.
Subpart C: Prohibitions				
201.141	Prohibition of Air Pollution	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 102.
201.142	Construction Permit Required	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(a)(1).
201.143	Operating Permits for New Sources	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(b)(1).
201.144	Operating Permits for Existing Sources	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(b)(2).
201.146	Exemptions From State Permit Requirements	12/23/13	03/13/15, 80 FR 13248.	
201.147	Former Permits	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(j).
201.148	Operation Without Compliance Program and Project Completion Schedule.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(a).
201.149	Operation During Malfunction, Breakdown or Startups.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(a).
201.150	Circumvention	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 109.
201.151	Design of Effluent Exhaust Systems	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 110.
Subpart D: Permit Applications and Review Process				
201.152	Contents of Application for Construction Permit.	06/23/98	01/03/00, 65 FR 14.	
201.156	Conditions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(a)(6).
201.157	Contents of Application for Operating Permit	06/23/98	01/03/00, 65 FR 14.	
201.158	Incomplete Applications	06/23/98	01/03/00, 65 FR 14.	
201.159	Signatures	06/23/98	01/03/00, 65 FR 14.	
201.160	Standards for Issuance	06/23/98	01/03/00, 65 FR 14.	

EPA-APPROVED ILLINOIS REGULATIONS AND STATUTES—Continued

Illinois citation	Title/subject	State effective date	EPA approval date	Comments
201.161	Conditions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(b)(7).
201.162	Duration	12/01/10	04/07/14, 79 FR 18997.	
201.163	Joint Construction and Operating Permits	06/23/98	01/03/00, 65 FR 14.	
201.164	Design Criteria	06/23/98	01/03/00, 65 FR 14.	
201.165	Hearings	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(e).
201.166	Revocation	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(f).
201.167	Revisions to Permits	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(g).
201.168	Appeals From Conditions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 103(k).
Subpart F: CAAPP Permits				
201.207	Applicability	06/23/98	01/03/00, 65 FR 14.	
Subpart H: Compliance Programs and Project Completion Schedules				
201.241	Contents of Compliance Program	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(b)(1).
201.242	Contents of Project Completion Schedule	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(b)(2, 3).
201.243	Standards for Approval	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(c).
201.244	Revisions	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(d).
201.245	Effects of Approval	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(e).
201.246	Records and Reports	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 104(f).
Subpart I: Malfunctions, Breakdowns or Startups				
201.261	Contents of Request for Permission To Operate During a Malfunction, Breakdown or Startup.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(b).
201.262	Standards for Granting Permission To Operate During a Malfunction, Breakdown or Startup.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(c).
201.263	Records and Reports	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(d).
201.264	Continued Operation or Startup Prior to Granting of Operating Permit.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(e).
201.265	Effect of Granting of Permission To Operate During a Malfunction, Breakdown or Start-up.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 105(f).
Subpart J: Monitoring and Testing				
201.281	Permit Monitoring Equipment Requirements	02/03/89	04/06/93, 58 FR 17780.	
201.282	Testing	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 106(b).
201.283	Records and Reports	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 106(c).
Subpart K: Records and Reports				
201.301	Records	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 107(a).
201.302	Reports	12/23/13	03/13/15, 80 FR 13248.	
Subpart L: Continuous Monitoring				
201.401	Continuous Monitoring Requirements	02/03/89	04/06/93, 58 FR 17780.	
201.402	Alternative Monitoring	02/03/89	04/06/93, 58 FR 17780.	
201.403	Exempt Sources	02/03/89	04/06/93, 58 FR 17780.	
201.404	Monitoring System Malfunction	02/03/89	04/06/93, 58 FR 17780.	
201.405	Excess Emission Reporting	02/03/89	04/06/93, 58 FR 17780.	
201.406	Data Reduction	02/03/89	04/06/93, 58 FR 17780.	
201.407	Retention of Information	02/03/89	04/06/93, 58 FR 17780.	
201.408	Compliance Schedules	02/03/89	04/06/93, 58 FR 17780.	
Part 203: Major Stationary Sources Construction and Modification				
Subpart A: General Provisions				
203.101	Definitions	04/30/93	09/27/95, 60 FR 49778.	
203.103	Actual Construction	03/22/88	12/17/92, 57 FR 59928.	
203.104	Actual Emissions	03/22/88	12/17/92, 57 FR 59928.	
203.107	Allowable Emissions	04/30/93	09/27/95, 60 FR 49778.	
203.110	Available Growth Margin	04/30/93	09/27/95, 60 FR 49778.	
203.112	Building, Structure and Facility	04/30/93	09/27/95, 60 FR 49778.	
203.113	Commence	03/22/88	12/17/92, 57 FR 59928.	
203.116	Construction	03/22/88	12/17/92, 57 FR 59928.	

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203.117	Dispersion Enhancement Techniques	03/22/88	12/17/92, 57 FR 59928.	
203.119	Emission Baseline	07/22/83	12/17/92, 57 FR 59928.	
203.121	Emission Offset	04/30/93	09/27/95, 60 FR 49778.	
203.122	Emissions Unit	04/30/93	09/27/95, 60 FR 49778.	
203.123	Federally Enforceable	04/30/93	09/27/95, 60 FR 49778.	
203.124	Fugitive Emissions	03/22/88	12/17/92, 57 FR 59928.	
203.125	Installation	03/22/88	12/17/92, 57 FR 59928.	
203.126	Lowest Achievable Emission Rate	04/30/93	09/27/95, 60 FR 49778.	
203.127	Nonattainment Area	03/22/88	12/17/92, 57 FR 59928.	
203.128	Potential To Emit	04/30/93	09/27/95, 60 FR 49778.	
203.131	Reasonable Further Progress	03/22/88	12/17/92, 57 FR 59928.	
203.134	Secondary Emissions	03/22/88	12/17/92, 57 FR 59928.	
203.136	Stationary Source	03/22/88	12/17/92, 57 FR 59928.	
203.150	Public Participation	04/30/93	09/27/95, 60 FR 49778.	
Subpart B: Major Stationary Sources in Nonattainment Areas				
203.201	Prohibition	04/30/93	09/27/95, 60 FR 49778.	
203.202	Coordination With Permit Requirement and Application Pursuant to 35 Ill. Adm. Code 201.	03/22/88	12/17/92, 57 FR 59928.	
203.203	Construction Permit Requirement and Application.	04/30/93	09/27/95, 60 FR 49778.	
203.205	Effect of Permits	03/22/88	12/17/92, 57 FR 59928.	
203.206	Major Stationary Source	03/10/98	05/13/03, 68 FR 25504.	
203.207	Major Modification of a Source	03/10/98	05/13/03, 68 FR 25504.	
203.208	Net Emission Determination	04/30/93	09/27/95, 60 FR 49778.	
203.209	Significant Emissions Determination	04/30/93	09/27/95, 60 FR 49778.	
203.210	Relaxation of a Source-Specific Limitation	03/22/88	12/17/92, 57 FR 59928.	
203.211	Permit Exemption Based on Fugitive Emissions.	03/22/88	12/17/92, 57 FR 59928.	
Subpart C: Requirements for Major Stationary Sources in Nonattainment Areas				
203.301	Lowest Achievable Emission Rate	03/10/98	05/13/03, 68 FR 25504.	
203.302	Maintenance of Reasonable Further Progress and Emission Offsets.	04/30/93	09/27/95, 60 FR 49778.	
203.303	Baseline and Emission Offsets Determination	04/30/93	09/27/95, 60 FR 49778.	
203.305	Compliance by Existing Sources	03/22/88	12/17/92, 57 FR 59928.	
203.306	Analysis of Alternatives	04/30/93	09/27/95, 60 FR 49778.	
Subpart F: Operation of a Major Stationary Source or Major Modification				
203.601	Lowest Achievable Emission Rate Compliance Requirement.	03/22/88	12/17/92, 57 FR 59928.	
203.602	Emission Offset Maintenance Requirement	03/22/88	12/17/92, 57 FR 59928.	
Subpart G: General Maintenance of Emission Offsets				
203.701	General Maintenance of Emission Offsets	03/22/88	12/17/92, 57 FR 59928.	
Subpart H: Offsets for Emission Increases From Rocket Engines and Motor Firing				
203.801	Offsetting by Alternative or Innovative Means	05/14/93	09/27/95, 60 FR 49778.	
Subchapter b: Alternative Reduction Program				
Part 205: Emissions Reduction Market System				
Subpart A: General Provisions				
205.100	Severability	11/25/97	10/15/01, 66 FR 52343.	
205.110	Purpose	11/25/97	10/15/01, 66 FR 52343.	
205.120	Abbreviations and Acronyms	06/13/05	07/07/08, 73 FR 38328.	
205.130	Definitions	06/13/05	07/07/08, 73 FR 38328.	
205.150	Emissions Management Periods	06/13/05	07/07/08, 73 FR 38328	Except 150(e).
Subpart B: Applicability				
205.200	Participating Source	06/13/05	07/07/08, 73 FR 38328.	
205.205	Exempt Source	06/13/05	07/07/08, 73 FR 38328.	

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205.210	New Participating Source	06/13/05	07/07/08, 73 FR 38328.	
205.220	Insignificant Emission Units	06/13/05	07/07/08, 73 FR 38328.	
205.225	Startup, Malfunction or Breakdown	11/25/97	10/15/01, 66 FR 52343.	
	Subpart C: Operational Implementation			
205.300	Seasonal Emissions Component of the Annual Emissions Report.	06/13/05	07/07/08, 73 FR 38328.	
205.310	ERMS Applications	06/13/05	07/07/08, 73 FR 38328.	
205.315	CAAPP Permits for ERMS Sources	06/13/05	07/07/08, 73 FR 38328.	
205.316	Federally Enforceable State Operating Permits for ERMS Sources.	06/13/05	07/07/08, 73 FR 38328.	
205.318	Certification for Exempt CAAPP Sources	06/13/05	07/07/08, 73 FR 38328.	
205.320	Baseline Emissions	06/13/05	07/07/08, 73 FR 38328.	
205.330	Emissions Determination Methods	06/13/05	07/07/08, 73 FR 38328.	
205.335	Sampling, Testing, Monitoring and Recordkeeping Practices.	06/13/05	07/07/08, 73 FR 38328.	
205.337	Changes in Emissions Determination Methods and Sampling, Testing, Monitoring and Recordkeeping Practices.	06/13/05	07/07/08, 73 FR 38328.	
	Subpart D: Seasonal Emissions Management			
205.400	Seasonal Emissions Allotment	06/13/05	07/07/08, 73 FR 38328.	
205.405	Exclusions From Further Reductions	06/13/05	07/07/08, 73 FR 38328.	
205.410	Participating Source Shutdowns	06/13/05	07/07/08, 73 FR 38328.	
	Subpart E: Alternative ATU Generation			
205.500	Emissions Reduction Generator	06/13/05	07/07/08, 73 FR 38328.	
205.510	Inter-Sector Transaction	06/13/05	07/07/08, 73 FR 38328.	
	Subpart F: Market Transactions			
205.600	ERMS Database	11/25/97	10/15/01, 66 FR 52343.	
205.610	Application for Transaction Account	06/13/05	07/07/08, 73 FR 38328.	
205.620	Account Officer	11/25/97	10/15/01, 66 FR 52343.	
205.630	ATU Transaction Procedures	11/25/97	10/15/01, 66 FR 52343.	
	Subpart G: Performance Accountability			
205.700	Compliance Accounting	06/13/05	07/07/08, 73 FR 38328.	
205.710	Alternative Compliance Market Account (ACMA).	11/25/97	10/15/01, 66 FR 52343.	
205.720	Emissions Excursion Compensation	11/25/97	10/15/01, 66 FR 52343.	
205.730	Excursion Reporting	06/13/05	07/07/08, 73 FR 38328.	
205.740	Enforcement Authority	11/25/97	10/15/01, 66 FR 52343.	
205.750	Emergency Conditions	06/13/05	07/07/08, 73 FR 38328.	
205.760	Market System Review Procedures	06/13/05	07/07/08, 73 FR 38328.	
	Subchapter c: Emission Standards and Limitations for Stationary Sources			
	Part 211: Definitions and General Provisions			
	Subpart A: General Provisions			
211.101	Incorporations by Reference	01/28/13	10/06/14, 79 FR 60070.	
211.102	Abbreviations and Conversion Factors	09/14/10	03/23/12, 77 FR 16940.	
	Subpart B: Definitions			
211.121	Other Definitions	09/27/93	09/09/94, 59 FR 46562.	
211.130	Accelacota	09/27/93	09/09/94, 59 FR 46562.	
211.150	Accumulator	09/27/93	09/09/94, 59 FR 46562.	
211.170	Acid Gases	09/27/93	09/09/94, 59 FR 46562.	
211.200	Acrylonitrile Butadiene Styrene (ABS) Welding.	09/14/10	03/23/12, 77 FR 16940.	
211.210	Actual Heat Input	09/27/93	09/09/94, 59 FR 46562.	
211.230	Adhesive	09/27/93	09/09/94, 59 FR 46562.	
211.233	Adhesion Primer	09/14/10	03/23/12, 77 FR 16940.	
211.235	Adhesive Primer	09/14/10	03/23/12, 77 FR 16940.	

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211.240	Adhesion Promoter	05/09/95	07/25/96, 61 FR 38577.	
211.250	Aeration	09/27/93	09/09/94, 59 FR 46562.	
211.260	Aerosol Adhesive and Adhesive Primer	09/14/10	03/23/12, 77 FR 16940.	
211.270	Aerosol Can Filling Line	01/18/94	10/21/96, 61 FR 54556.	
211.290	Afterburner	09/27/93	09/09/94, 59 FR 46562.	
211.310	Air Contaminant	09/27/93	09/09/94, 59 FR 46562.	
211.330	Air Dried Coatings	09/27/93	09/09/94, 59 FR 46562.	
211.350	Air Oxidation Process	09/27/93	09/09/94, 59 FR 46562.	
211.370	Air Pollutant	09/27/93	09/09/94, 59 FR 46562.	
211.390	Air Pollution	09/27/93	09/09/94, 59 FR 46562.	
211.410	Air Pollution Control Equipment	09/27/93	09/09/94, 59 FR 46562.	
211.430	Air Suspension Coater/Dryer	09/27/93	09/09/94, 59 FR 46562.	
211.450	Airless Spray	09/27/93	09/09/94, 59 FR 46562.	
211.470	Air Assisted Airless Spray	09/27/93	09/09/94, 59 FR 46562.	
211.474	Alcohol	05/09/95	11/08/95, 60 FR 56238.	
211.481	Ammunition Sealant	09/14/10	03/23/12, 77 FR 16940.	
211.490	Annual Grain Through Put	09/27/93	09/09/94, 59 FR 46562.	
211.492	Antifoulant Coating	09/14/10	03/23/12, 77 FR 16940.	
211.493	Antifouling Sealer/Tie Coat	07/27/11	03/23/12, 77 FR 16940.	
211.495	Anti-Glare/Safety Coating	05/09/95	07/25/96, 61 FR 38577.	
211.510	Application Area	09/27/93	09/09/94, 59 FR 46562.	
211.530	Architectural Coating	09/27/93	09/09/94, 59 FR 46562.	
211.540	Architectural Structure	09/14/10	03/23/12, 77 FR 16940.	
211.550	As Applied	09/27/93	09/09/94, 59 FR 46562.	
211.560	As-Applied Fountain Solution	05/09/95	11/08/95, 60 FR 56238.	
211.570	Asphalt	09/27/93	09/09/94, 59 FR 46562.	
211.590	Asphalt Prime Coat	09/27/93	09/09/94, 59 FR 46562.	
211.610	Automobile	09/27/93	09/09/94, 59 FR 46562.	
211.630	Automobile or Light Duty Truck Assembly Source or Automobile or Light Duty Truck Manufacturing Plant.	09/27/93	09/09/94, 59 FR 46562.	
211.650	Automobile or Light Duty Truck Refinishing	09/27/93	09/09/94, 59 FR 46562.	
211.660	Automotive/Transportation Plastic Parts	05/09/95	10/26/95, 60 FR 54807.	
211.670	Baked Coatings	05/09/95	10/26/95, 60 FR 54807.	
211.685	Basecoat/Clearcoat System	05/09/95	07/25/96, 61 FR 38577.	
211.690	Batch Loading	09/27/93	09/09/94, 59 FR 46562.	
211.695	Batch Operation	05/22/95	04/02/96, 61 FR 14484.	
211.696	Batch Process Train	05/22/95	04/02/96, 61 FR 14484.	
211.710	Bead Dipping	09/27/93	09/09/94, 59 FR 46562.	
211.715	Bedliner	09/14/10	03/23/12, 77 FR 16940.	
211.730	Binders	09/27/93	09/09/94, 59 FR 46562.	
211.735	Black Coating	09/14/10	03/23/12, 77 FR 16940.	
211.740	Brakehorsepower (rated-bhp)	09/25/07	06/26/09, 74 FR 30466.	
211.750	British Thermal Unit	09/27/93	09/09/94, 59 FR 46562.	
211.770	Brush or Wipe Coating	09/27/93	09/09/94, 59 FR 46562.	
211.790	Bulk Gasoline Plant	09/27/93	09/09/94, 59 FR 46562.	
211.810	Bulk Gasoline Terminal	09/27/93	09/09/94, 59 FR 46562.	
211.820	Business Machine Plastic Parts	09/14/10	03/23/12, 77 FR 16940.	
211.825	Camouflage Coating	09/14/10	03/23/12, 77 FR 16940.	
211.830	Can	09/27/93	09/09/94, 59 FR 46562.	
211.850	Can Coating	09/27/93	09/09/94, 59 FR 46562.	
211.870	Can Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.880	Cap Sealant	09/14/10	03/23/12, 77 FR 16940.	
211.890	Capture	09/27/93	09/09/94, 59 FR 46562.	
211.910	Capture Device	09/27/93	09/09/94, 59 FR 46562.	
211.930	Capture Efficiency	09/27/93	09/09/94, 59 FR 46562.	
211.950	Capture System	09/27/93	09/09/94, 59 FR 46562.	
211.954	Cavity Wax	09/14/10	03/23/12, 77 FR 16940.	
211.955	Cement	03/15/01	11/08/01, 66 FR 56449.	
211.960	Cement Kiln	03/15/01	11/08/01, 66 FR 56449.	
211.965	Ceramic Tile Installation Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.970	Certified Investigation	09/27/93	09/09/94, 59 FR 46562.	
211.980	Chemical Manufacturing Process Unit	05/09/95	03/23/98, 63 FR 13784.	
211.990	Choke Loading	09/27/93	09/09/94, 59 FR 46562.	
211.1000	Class II Finish	06/25/10	03/23/12, 77 FR 16940.	
211.1010	Clean Air Act	09/27/93	09/09/94, 59 FR 46562.	
211.1050	Cleaning and Separating Operation	09/27/93	09/09/94, 59 FR 46562.	
211.1070	Cleaning Materials	01/18/94	10/21/96, 61 FR 54556.	
211.1090	Clear Coating	09/27/93	09/09/94, 59 FR 46562.	
211.1110	Clear Topcoat	09/27/93	09/09/94, 59 FR 46562.	

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211.1120	Clinker	03/15/01	11/08/01, 66 FR 56449.	
211.1128	Closed Molding	09/14/10	03/23/12, 77 FR 16940.	
211.1130	Closed Purge System	09/27/93	09/09/94, 59 FR 46562.	
211.1150	Closed Vent System	09/27/93	09/09/94, 59 FR 46562.	
211.1170	Coal Refuse	09/27/93	09/09/94, 59 FR 46562.	
211.1190	Coating	09/27/93	09/09/94, 59 FR 46562.	
211.1210	Coating Applicator	09/27/93	09/09/94, 59 FR 46562.	
211.1230	Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.1250	Coating Plant	09/27/93	09/09/94, 59 FR 46562.	
211.1270	Coil Coating	09/27/93	09/09/94, 59 FR 46562.	
211.1290	Coil Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.1310	Cold Cleaning	09/27/93	09/09/94, 59 FR 46562.	
211.1330	Complete Combustion	09/27/93	09/09/94, 59 FR 46562.	
211.1350	Component	09/27/93	09/09/94, 59 FR 46562.	
211.1370	Concrete Curing Compounds	09/27/93	09/09/94, 59 FR 46562.	
211.1390	Concentrated Nitric Acid Manufacturing Process.	09/27/93	09/09/94, 59 FR 46562.	
211.1410	Condensate	09/27/93	09/09/94, 59 FR 46562.	
211.1430	Condensible PM 10	09/27/93	09/09/94, 59 FR 46562.	
211.1455	Contact Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.1467	Continuous Coater	02/02/98	05/19/98, 63 FR 27489.	
211.1470	Continuous Process	09/27/93	09/09/94, 59 FR 46562.	
211.1490	Control Device	09/27/93	09/09/94, 59 FR 46562.	
211.1510	Control Device Efficiency	09/27/93	09/09/94, 59 FR 46562.	
211.1520	Conventional Air Spray	02/02/98	05/19/98, 63 FR 27489.	
211.1530	Conventional Soybean Crushing Source	09/27/93	09/09/94, 59 FR 46562.	
211.1550	Conveyorized Degreasing	09/27/93	09/09/94, 59 FR 46562.	
211.1560	Cove Base	09/14/10	03/23/12, 77 FR 16940.	
211.1565	Cove Base Installation Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.1570	Crude Oil	09/27/93	09/09/94, 59 FR 46562.	
211.1590	Crude Oil Gathering	09/27/93	09/09/94, 59 FR 46562.	
211.1610	Crushing	09/27/93	09/09/94, 59 FR 46562.	
211.1630	Custody Transfer	09/27/93	09/09/94, 59 FR 46562.	
211.1650	Cutback Asphalt	09/27/93	09/09/94, 59 FR 46562.	
211.1655	Cyanoacrylate Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.1670	Daily Weighted Average VOM Content	09/27/93	09/09/94, 59 FR 46562.	
211.1690	Day	09/27/93	09/09/94, 59 FR 46562.	
211.1700	Deadener	09/14/10	03/23/12, 77 FR 16940.	
211.1710	Degreaser	09/27/93	09/09/94, 59 FR 46562.	
211.1730	Delivery Vessel	09/27/93	09/09/94, 59 FR 46562.	
211.1740	Diesel Engine	09/25/07	06/26/09, 74 FR 30466.	
211.1745	Digital Printing	06/25/10	03/23/12, 77 FR 16940.	
211.1750	Dip Coating	09/27/93	09/09/94, 59 FR 46562.	
211.1770	Distillate Fuel Oil	09/27/93	09/09/94, 59 FR 46562.	
211.1780	Distillation Unit	05/09/95	03/23/98, 63 FR 13784.	
211.1790	Drum	09/27/93	09/09/94, 59 FR 46562.	
211.1810	Dry Cleaning Operation or Dry Cleaning Facility.	09/27/93	09/09/94, 59 FR 46562.	
211.1830	Dump Pit Area	09/27/93	09/09/94, 59 FR 46562.	
211.1850	Effective Grate Area	09/27/93	09/09/94, 59 FR 46562.	
211.1870	Effluent Water Separator	09/27/93	09/09/94, 59 FR 46562.	
211.1872	Ejection Cartridge Sealant	09/14/10	03/23/12, 77 FR 16940.	
211.1875	Elastomeric Materials	05/09/95	07/25/96, 61 FR 38577.	
211.1876	Electric Dissipating Coating	09/14/10	03/23/12, 77 FR 16940.	
211.1877	Electric-Insulating Varnish	09/14/10	03/23/12, 77 FR 16940.	
211.1878	Electrical Apparatus Component	06/25/10	03/23/12, 77 FR 16940.	
211.1880	Electrical Switchgear Compartment Coating	09/14/10	03/23/12, 77 FR 16940.	
211.1882	Electrodeposition Primer (EDP)	09/14/10	03/23/12, 77 FR 16940.	
211.1883	Electromagnetic Interference/Radio Frequency Interference (EMI/RFI) Shielding Coatings.	09/14/10	03/23/12, 77 FR 16940.	
211.1885	Electronic Component	06/25/10	03/23/12, 77 FR 16940.	
211.1890	Electrostatic Bell or Disc Spray	09/27/93	09/09/94, 59 FR 46562.	
211.1900	Electrostatic Prep Coat	05/09/95	10/26/95, 60 FR 54807.	
211.1910	Electrostatic Spray	09/27/93	09/09/94, 59 FR 46562.	
211.1920	Emergency or Standby Unit	09/25/07	06/26/09, 74 FR 30466.	
211.1930	Emission Rate	09/27/93	09/09/94, 59 FR 46562.	
211.1950	Emission Unit	09/27/93	09/09/94, 59 FR 46562.	
211.1970	Enamel	09/27/93	09/09/94, 59 FR 46562.	
211.1990	Enclose	09/27/93	09/09/94, 59 FR 46562.	

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211.2010	End Sealing Compound Coat	09/27/93	09/09/94, 59 FR 46562.	
211.2030	Enhanced Under-the-Cup Fill	01/18/94	10/21/96, 61 FR 54556.	
211.2040	Etching Filler	09/14/10	03/23/12, 77 FR 16940.	
211.2050	Ethanol Blend Gasoline	09/27/93	09/09/94, 59 FR 46562.	
211.2055	Ethylene Propylenediene Monomer (DPDM) Roof Membrane.	09/14/10	03/23/12, 77 FR 16940.	
211.2070	Excess Air	09/27/93	09/09/94, 59 FR 46562.	
211.2090	Excessive Release	09/27/93	09/09/94, 59 FR 46562.	
211.2130	Existing Grain Handling Operation	09/27/93	09/09/94, 59 FR 46562.	
211.2150	Exterior Base Coat	09/27/93	09/09/94, 59 FR 46562.	
211.2170	Exterior End Coat	09/27/93	09/09/94, 59 FR 46562.	
211.2190	External Floating Roof	09/27/93	09/09/94, 59 FR 46562.	
211.2200	Extreme High-Gloss Coating	07/27/11	03/23/12, 77 FR 16940.	
211.2210	Extreme Performance Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2230	Fabric Coating	09/27/93	09/09/94, 59 FR 46562.	
211.2250	Fabric Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.2270	Federally Enforceable Limitations and Conditions.	09/27/93	09/09/94, 59 FR 46562.	
211.2285	Feed Mill	06/17/97	02/17/00, 65 FR 8064.	
211.2300	Fill	11/15/94	08/08/96, 61 FR 41338.	
211.2310	Final Repair Coat	09/14/10	03/23/12, 77 FR 16940.	
211.2320	Finish Primer Surfacer	09/14/10	03/23/12, 77 FR 16940.	
211.2330	Firebox	09/27/93	09/09/94, 59 FR 46562.	
211.2350	Fixed Roof Tank	09/27/93	09/09/94, 59 FR 46562.	
211.2358	Flat Wood Paneling	07/27/11	03/23/12, 77 FR 16940.	
211.2359	Flat Wood Paneling Coating Line	06/25/10	03/23/12, 77 FR 16940.	
211.2360	Flexible Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2365	Flexible Operation Unit	05/09/95	03/23/98, 63 FR 13784.	
211.2368	Flexible Packaging	06/25/10	03/23/12, 77 FR 16940.	
211.2369	Flexible Vinyl	09/14/10	03/23/12, 77 FR 16940.	
211.2370	Flexographic Printing	09/27/93	09/09/94, 59 FR 46562.	
211.2390	Flexographic Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.2410	Floating Roof	09/27/93	09/09/94, 59 FR 46562.	
211.2415	Fog Coat	09/14/10	03/23/12, 77 FR 16940.	
211.2430	Fountain Solution	09/27/93	09/09/94, 59 FR 46562.	
211.2450	Freeboard Height	09/27/93	09/09/94, 59 FR 46562.	
211.2470	Fuel Combustion Emission Unit or Fuel Combustion Emission Source.	09/27/93	09/09/94, 59 FR 46562.	
211.2490	Fugitive Particulate Matter	09/27/93	09/09/94, 59 FR 46562.	
211.2510	Full Operating Flowrate	09/27/93	09/09/94, 59 FR 46562.	
211.2525	Gasket/Gasket Sealing Material	09/14/10	03/23/12, 77 FR 16940.	
211.2530	Gas Service	09/27/93	09/09/94, 59 FR 46562.	
211.2550	Gas/Gas Method	09/27/93	09/09/94, 59 FR 46562.	
211.2570	Gasoline	09/27/93	09/09/94, 59 FR 46562.	
211.2590	Gasoline Dispensing Operation or Gasoline Dispensing Facility.	09/27/93	09/09/94, 59 FR 46562.	
211.2610	Gel Coat	01/18/94	10/21/96, 61 FR 54556.	
211.2615	General Work Surface	06/25/10	03/23/12, 77 FR 16940.	
211.2622	Glass Bonding Primer	09/14/10	03/23/12, 77 FR 16940.	
211.2630	Gloss Reducers	05/09/95	10/26/95, 60 FR 54807.	
211.2650	Grain	09/27/93	09/09/94, 59 FR 46562.	
211.2670	Grain Drying Operation	09/27/93	09/09/94, 59 FR 46562.	
211.2690	Grain Handling and Conditioning Operation	09/27/93	09/09/94, 59 FR 46562.	
211.2710	Grain Handling Operation	09/27/93	09/09/94, 59 FR 46562.	
211.2730	Green Tire Spraying	09/27/93	09/09/94, 59 FR 46562.	
211.2750	Green Tires	09/27/93	09/09/94, 59 FR 46562.	
211.2770	Gross Heating Value	09/27/93	09/09/94, 59 FR 46562.	
211.2790	Gross Vehicle Weight Rating	09/27/93	09/09/94, 59 FR 46562.	
211.2800	Hardwood Plywood	07/27/11	03/23/12, 77 FR 16940.	
211.2810	Heated Airless Spray	09/27/93	09/09/94, 59 FR 46562.	
211.2825	Heat-Resistant Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2830	Heatset	06/25/10	03/23/12, 77 FR 16940.	
211.2840	Heatset Web Letterpress Printing Line	06/25/10	03/23/12, 77 FR 16940.	
211.2850	Heatset Web Offset Lithographic Printing Line	05/09/95	11/08/95, 60 FR 56238.	
211.2870	Heavy Liquid	01/28/13	10/06/14, 79 FR 60070.	
211.2890	Heavy Metals	09/27/93	09/09/94, 59 FR 46562.	
211.2910	Heavy Off Highway Vehicle Products	09/27/93	09/09/94, 59 FR 46562.	
211.2930	Heavy Off Highway Vehicle Products Coating	09/27/93	09/09/94, 59 FR 46562.	
211.2950	Heavy Off Highway Vehicle Products Coating Line.	09/27/93	09/09/94, 59 FR 46562.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
211.2955	High Bake Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2956	High Build Primer Surfacer	09/14/10	03/23/12, 77 FR 16940.	
211.2958	High Gloss Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2960	High-Performance Architectural Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2965	High Precision Optic	06/25/10	03/23/12, 77 FR 16940.	
211.2970	High Temperature Aluminum Coating	09/27/93	09/09/94, 59 FR 46562.	
211.2980	High Temperature Coating	09/14/10	03/23/12, 77 FR 16940.	
211.2990	High Volume Low Pressure (HVLP) Spray	09/27/93	09/09/94, 59 FR 46562.	
211.3010	Hood	09/27/93	09/09/94, 59 FR 46562.	
211.3030	Hot Well	09/27/93	09/09/94, 59 FR 46562.	
211.3050	Housekeeping Practices	09/27/93	09/09/94, 59 FR 46562.	
211.3070	Incinerator	09/27/93	09/09/94, 59 FR 46562.	
211.3090	Indirect Heat Transfer	09/27/93	09/09/94, 59 FR 46562.	
211.3095	Indoor Floor Covering Installation Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.3110	Ink	09/27/93	09/09/94, 59 FR 46562.	
211.3120	In-Line Repair	09/14/10	03/23/12, 77 FR 16940.	
211.3130	In-Process Tank	09/27/93	09/09/94, 59 FR 46562.	
211.3150	In-Situ Sampling Systems	09/27/93	09/09/94, 59 FR 46562.	
211.3170	Interior Body Spray Coat	09/27/93	09/09/94, 59 FR 46562.	
211.3190	Internal Floating Roof	09/27/93	09/09/94, 59 FR 46562.	
211.3210	Internal Transferring Area	09/27/93	09/09/94, 59 FR 46562.	
211.3215	Janitorial Cleaning	06/25/10	03/23/12, 77 FR 16940.	
211.3230	Lacquers	09/27/93	09/09/94, 59 FR 46562.	
211.3240	Laminate	09/14/10	03/23/12, 77 FR 16940.	
211.3250	Large Appliance	09/27/93	09/09/94, 59 FR 46562.	
211.3270	Large Appliance Coating	09/27/93	09/09/94, 59 FR 46562.	
211.3290	Large Appliance Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.3300	Lean-Burn Engine	09/25/07	06/26/09, 74 FR 30466.	
211.3305	Letterpress Printing Line	06/25/10	03/23/12, 77 FR 16940.	
211.3310	Light Liquid	09/27/93	09/09/94, 59 FR 46562.	
211.3330	Light Duty Truck	09/27/93	09/09/94, 59 FR 46562.	
211.3350	Light Oil	09/27/93	09/09/94, 59 FR 46562.	
211.3370	Liquid/Gas Method	09/27/93	09/09/94, 59 FR 46562.	
211.3390	Liquid Mounted Seal	09/27/93	09/09/94, 59 FR 46562.	
211.3410	Liquid Service	09/27/93	09/09/94, 59 FR 46562.	
211.3430	Liquids Dripping	09/27/93	09/09/94, 59 FR 46562.	
211.3450	Lithographic Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.3470	Load Out Area	09/27/93	09/09/94, 59 FR 46562.	
211.3480	Loading Event	10/25/94	04/03/95, 60 FR 16801.	
211.3483	Long Dry Kiln	03/15/01	11/08/01, 66 FR 56449.	
211.3485	Long Wet Kiln	03/15/01	11/08/01, 66 FR 56449.	
211.3487	Low-NO_X Burner	03/15/01	11/08/01, 66 FR 56449.	
211.3490	Low Solvent Coating	09/27/93	09/09/94, 59 FR 46562.	
211.3505	Lubricating Wax/Compound	09/14/10	03/23/12, 77 FR 16940.	
211.3510	Magnet Wire	09/27/93	09/09/94, 59 FR 46562.	
211.3530	Magnet Wire Coating	09/27/93	09/09/94, 59 FR 46562.	
211.3550	Magnet Wire Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.3555	Maintenance Cleaning	06/25/10	03/23/12, 77 FR 16940.	
211.3570	Major Dump Pit	09/27/93	09/09/94, 59 FR 46562.	
211.3590	Major Metropolitan Area (MMA)	09/27/93	09/09/94, 59 FR 46562.	
211.3610	Major Population Area (MPA)	09/27/93	09/09/94, 59 FR 46562.	
211.3630	Manufacturing Process	09/27/93	09/09/94, 59 FR 46562.	
211.3650	Marine Terminal	10/25/94	04/03/95, 60 FR 16801.	
211.3660	Marine Vessel	10/25/94	04/03/95, 60 FR 16801.	
211.3665	Mask Coating	09/14/10	03/23/12, 77 FR 16940.	
211.3670	Material Recovery Section	09/27/93	09/09/94, 59 FR 46562.	
211.3690	Maximum Theoretical Emissions	09/27/93	09/09/94, 59 FR 46562.	
211.3695	Maximum True Vapor Pressure	11/15/94	08/08/96, 61 FR 41338.	
211.3705	Medical Device	06/25/10	03/23/12, 77 FR 16940.	
211.3707	Medical Device and Pharmaceutical Manufacturing.	06/25/10	03/23/12, 77 FR 16940.	
211.3710	Metal Furniture	09/27/93	09/09/94, 59 FR 46562.	
211.3730	Metal Furniture Coating	09/27/93	09/09/94, 59 FR 46562.	
211.3750	Metal Furniture Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.3760	Metallic Coating	09/14/10	03/23/12, 77 FR 16940.	
211.3770	Metallic Shoe Type Seal	09/27/93	09/09/94, 59 FR 46562.	
211.3775	Metal to Urethane/Rubber Molding or Casting Adhesive.	09/14/10	03/23/12, 77 FR 16940.	
211.3780	Mid-Kiln Firing	03/15/01	11/08/01, 66 FR 56449.	
211.3785	Military Specification Coating	09/14/10	03/23/12, 77 FR 16940.	

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211.3790	Miscellaneous Fabricated Product Manufacturing Process.	09/27/93	09/09/94, 59 FR 46562.	
211.3810	Miscellaneous Formulation Manufacturing Process.	09/27/93	09/09/94, 59 FR 46562.	
211.3820	Miscellaneous Industrial Adhesive Application Operation.	09/14/10	03/23/12, 77 FR 16940.	
211.3830	Miscellaneous Metal Parts and Products	09/27/93	09/09/94, 59 FR 46562.	
211.3850	Miscellaneous Metal Parts and Products Coating.	09/27/93	09/09/94, 59 FR 46562.	
211.3870	Miscellaneous Metal Parts or Products Coating Line.	09/27/93	09/09/94, 59 FR 46562.	
211.3890	Miscellaneous Organic Chemical Manufacturing Process.	09/27/93	09/09/94, 59 FR 46562.	
211.3910	Mixing Operation	09/27/93	09/09/94, 59 FR 46562.	
211.3915	Mobile Equipment	05/09/95	07/25/96, 61 FR 38577.	
211.3925	Mold Seal Coating	09/14/10	03/23/12, 77 FR 16940.	
211.3930	Monitor	09/27/93	09/09/94, 59 FR 46562.	
211.3950	Monomer	01/18/94	10/21/96, 61 FR 54556.	
211.3960	Motor Vehicles	05/09/95	07/25/96, 61 FR 38577.	
211.3961	Motor Vehicle Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.3965	Motor Vehicle Refinishing	05/09/95	07/25/96, 61 FR 38577.	
211.3966	Motor Vehicle Weatherstrip Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.3967	Mouth Waterproofing Sealant	09/14/10	03/23/12, 77 FR 16940.	
211.3968	Multi-Colored Coating	09/14/10	03/23/12, 77 FR 16940.	
211.3969	Multi-Component Coating	09/14/10	03/23/12, 77 FR 16940.	
211.3970	Multiple Package Coating	09/27/93	09/09/94, 59 FR 46562.	
211.3975	Multipurpose Construction Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.3985	Natural Finish Hardwood Plywood Panel	07/27/11	03/23/12, 77 FR 16940.	
211.3990	New Grain Drying Operation	09/27/93	09/09/94, 59 FR 46562.	
211.4010	New Grain Handling Operation	09/27/93	09/09/94, 59 FR 46562.	
211.4030	No Detectable Volatile Organic Material Emissions.	09/27/93	09/09/94, 59 FR 46562.	
211.4050	Non-Contact Process Water Cooling Tower	01/18/94	10/21/96, 61 FR 54556.	
211.4052	Non-Convertible Coating	09/14/10	03/23/12, 77 FR 16940.	
211.4055	Non-Flexible Coating	05/09/95	10/26/95, 60 FR 54807.	
211.4065	Non-Heatset	06/25/10	03/23/12, 77 FR 16940.	
211.4067	NO_X Trading Program	04/17/01	11/08/01, 66 FR 56449.	
211.4070	Offset	09/27/93	09/09/94, 59 FR 46562.	
211.4080	One-Component Coating	09/14/10	03/23/12, 77 FR 16940.	
211.4090	One Hundred Percent Acid	09/27/93	09/09/94, 59 FR 46562.	
211.4110	One Turn Storage Space	09/27/93	09/09/94, 59 FR 46562.	
211.4130	Opacity	09/27/93	09/09/94, 59 FR 46562.	
211.4150	Opaque Stains	09/27/93	09/09/94, 59 FR 46562.	
211.4170	Open Top Vapor Degreasing	09/27/93	09/09/94, 59 FR 46562.	
211.4190	Open Ended Valve	09/27/93	09/09/94, 59 FR 46562.	
211.4210	Operator of a Gasoline Dispensing Operation or Operator of a Gasoline Dispensing Facility.	09/27/93	09/09/94, 59 FR 46562.	
211.4220	Optical Coating	09/14/10	03/23/12, 77 FR 16940.	
211.4230	Organic Compound	09/27/93	09/09/94, 59 FR 46562.	
211.4250	Organic Material and Organic Materials	10/19/95	03/21/96, 61 FR 11550.	
211.4260	Organic Solvent	10/19/95	03/21/96, 61 FR 11550.	
211.4270	Organic Vapor	09/27/93	09/09/94, 59 FR 46562.	
211.4285	Outdoor Floor Covering Installation Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.4290	Oven	09/27/93	09/09/94, 59 FR 46562.	
211.4310	Overall Control	09/27/93	09/09/94, 59 FR 46562.	
211.4330	Overvarnish	09/27/93	09/09/94, 59 FR 46562.	
211.4350	Owner of a Gasoline Dispensing Operation or Owner of a Gasoline Dispensing Facility.	09/27/93	09/09/94, 59 FR 46562.	
211.4370	Owner or Operator	09/27/93	09/09/94, 59 FR 46562.	
211.4390	Packaging Rotogravure Printing	09/27/93	09/09/94, 59 FR 46562.	
211.4410	Packaging Rotogravure Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.4430	Pail	09/27/93	09/09/94, 59 FR 46562.	
211.4450	Paint Manufacturing Source or Paint Manufacturing Plant.	09/27/93	09/09/94, 59 FR 46562.	
211.4455	Pan-Backing Coating	09/14/10	03/23/12, 77 FR 16940.	
211.4460	Panel	07/27/11	03/23/12, 77 FR 16940.	
211.4470	Paper Coating	09/27/93	09/09/94, 59 FR 46562.	
211.4490	Paper Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.4510	Particulate Matter	09/27/93	09/09/94, 59 FR 46562.	

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211.4530	Parts per Million (Volume) or Ppm (VOL)	09/27/93	09/09/94, 59 FR 46562.	
211.4540	Perimeter Bonded Sheet Flooring	09/14/10	03/23/12, 77 FR 16940.	
211.4550	Person	09/27/93	09/09/94, 59 FR 46562.	
211.4590	Petroleum	09/27/93	09/09/94, 59 FR 46562.	
211.4610	Petroleum Liquid	10/19/95	03/21/96, 61 FR 11550.	
211.4630	Petroleum Refinery	09/27/93	09/09/94, 59 FR 46562.	
211.4650	Pharmaceutical	09/27/93	09/09/94, 59 FR 46562.	
211.4670	Pharmaceutical Coating Operation	09/27/93	09/09/94, 59 FR 46562.	
211.4690	Photochemically Reactive Material	09/27/93	09/09/94, 59 FR 46562.	
211.4710	Pigmented Coatings	09/27/93	09/09/94, 59 FR 46562.	
211.4730	Plant	09/27/93	09/09/94, 59 FR 46562.	
211.4735	Plastic	09/14/10	03/23/12, 77 FR 16940.	
211.4740	Plastic Part	05/09/95	10/26/95, 60 FR 54807.	
211.4750	Plasticizers	09/27/93	09/09/94, 59 FR 46562.	
211.4760	Plastic Solvent Welding Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.4765	Plastic Solvent Welding Adhesive Primer	09/14/10	03/23/12, 77 FR 16940.	
211.4768	Pleasure Craft	09/14/10	03/23/12, 77 FR 16940.	
211.4769	Pleasure Craft Surface Coating	09/14/10	03/23/12, 77 FR 16940.	
211.4770	PM 10	09/27/93	09/09/94, 59 FR 46562.	
211.4790	Pneumatic Rubber Tire Manufacture	09/27/93	09/09/94, 59 FR 46562.	
211.4810	Polybasic Organic Acid Partial Oxidation Manufacturing Process.	09/27/93	09/09/94, 59 FR 46562.	
211.4830	Polyester Resin Material(s)	01/18/94	10/21/96, 61 FR 54556.	
211.4850	Polyester Resin Products Manufacturing Process.	01/18/94	10/21/96, 61 FR 54556.	
211.4870	Polystyrene Plant	09/27/93	09/09/94, 59 FR 46562.	
211.4890	Polystyrene Resin	09/27/93	09/09/94, 59 FR 46562.	
211.4895	Polyvinyl Chloride Plastic (PVC Plastic)	09/14/10	03/23/12, 77 FR 16940.	
211.4900	Porous Material	09/14/10	03/23/12, 77 FR 16940.	
211.4910	Portable Grain Handling Equipment	09/27/93	09/09/94, 59 FR 46562.	
211.4930	Portland Cement Manufacturing Process Emission Source.	09/27/93	09/09/94, 59 FR 46562.	
211.4950	Portland Cement Process or Portland Cement Manufacturing Plant.	09/27/93	09/09/94, 59 FR 46562.	
211.4970	Potential To Emit	01/18/94	10/21/96, 61 FR 54556.	
211.4990	Power Driven Fastener Coating	09/27/93	09/09/94, 59 FR 46562.	
211.5010	Precoat	05/09/95	07/25/96, 61 FR 38577.	
211.5012	Prefabricated Architectural Coating	09/14/10	03/23/12, 77 FR 16940.	
211.5015	Preheater Kiln	03/15/01	11/08/01, 66 FR 56449.	
211.5020	Preheater/Precalciner Kiln	03/15/01	11/08/01, 66 FR 56449.	
211.5030	Pressure Release	09/27/93	09/09/94, 59 FR 46562.	
211.5050	Pressure Tank	09/27/93	09/09/94, 59 FR 46562.	
211.5060	Pressure/Vacuum Relief Valve	09/21/94	01/27/95, 60 FR 5318.	
211.5061	Pretreatment Coating	09/14/10	03/23/12, 77 FR 16940.	
211.5062	Pretreatment Wash Primer	09/14/10	03/23/12, 77 FR 16940.	
211.5065	Primary Product	05/09/95	03/23/98, 63 FR 13784.	
211.5070	Prime Coat	09/27/93	09/09/94, 59 FR 46562.	
211.5075	Primer Sealant	09/14/10	03/23/12, 77 FR 16940.	
211.5080	Primer Sealer	05/09/95	07/25/96, 61 FR 38577.	
211.5090	Primer Surfacer Coat	09/14/10	03/23/12, 77 FR 16940.	
211.5110	Primer Surfacer Operation	09/27/93	09/09/94, 59 FR 46562.	
211.5130	Primers	09/27/93	09/09/94, 59 FR 46562.	
211.5140	Printed Interior Panel	07/27/11	03/23/12, 77 FR 16940.	
211.5150	Printing	09/27/93	09/09/94, 59 FR 46562.	
211.5170	Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.5185	Process Emission Source	09/27/93	09/09/94, 59 FR 46562.	
211.5190	Process Emission Unit	09/27/93	09/09/94, 59 FR 46562.	
211.5210	Process Unit	09/27/93	09/09/94, 59 FR 46562.	
211.5230	Process Unit Shutdown	09/27/93	09/09/94, 59 FR 46562.	
211.5245	Process Vent	05/22/95	04/02/96, 61 FR 14484.	
211.5250	Process Weight Rate	09/27/93	09/09/94, 59 FR 46562.	
211.5270	Production Equipment Exhaust System	09/27/93	09/09/94, 59 FR 46562.	
211.5310	Publication Rotogravure Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.5330	Purged Process Fluid	09/27/93	09/09/94, 59 FR 46562.	
211.5335	Radiation Effect Coating	06/25/10	03/23/12, 77 FR 16940.	
211.5350	Reactor	09/27/93	09/09/94, 59 FR 46562.	
211.5370	Reasonably Available Control Technology (RACT).	09/27/93	09/09/94, 59 FR 46562.	
211.5390	Reclamation System	01/18/94	10/21/96, 61 FR 54556.	
211.5400	Red Coating	09/14/10	03/23/12, 77 FR 16940.	

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211.5410	Refiner	09/27/93	09/09/94, 59 FR 46562.	
211.5430	Refinery Fuel Gas	09/27/93	09/09/94, 59 FR 46562.	
211.5450	Refinery Fuel Gas System	09/27/93	09/09/94, 59 FR 46562.	
211.5470	Refinery Unit or Refinery Process Unit	09/27/93	09/09/94, 59 FR 46562.	
211.5480	Reflective Argent Coating	05/09/95	10/26/95, 60 FR 54807.	
211.5490	Refrigerated Condenser	09/27/93	09/09/94, 59 FR 46562.	
211.5500	Regulated Air Pollutant	12/07/93	04/05/95, 60 FR 17229.	
211.5510	Reid Vapor Pressure	01/28/13	10/06/14, 79 FR 60070.	
211.5520	Reinforced Plastic Composite	09/14/10	03/23/12, 77 FR 16940.	
211.5530	Repair	01/18/94	10/21/96, 61 FR 54556.	
211.5535	Repair Cleaning	06/25/10	03/23/12, 77 FR 16940.	
211.5550	Repair Coat	09/14/10	03/23/12, 77 FR 16940.	
211.5570	Repaired	09/27/93	09/09/94, 59 FR 46562.	
211.5585	Research and Development Operation	06/25/10	03/23/12, 77 FR 16940.	
211.5590	Residual Fuel Oil	09/27/93	09/09/94, 59 FR 46562.	
211.5600	Resist Coat	05/09/95	10/26/95, 60 FR 54807.	
211.5610	Restricted Area	09/27/93	09/09/94, 59 FR 46562.	
211.5630	Retail Outlet	09/27/93	09/09/94, 59 FR 46562.	
211.5640	Rich-Burn Engine	09/25/07	06/26/09, 74 FR 30466.	
211.5650	Ringelmann Chart	09/27/93	09/09/94, 59 FR 46562.	
211.5670	Roadway	09/27/93	09/09/94, 59 FR 46562.	
211.5690	Roll Coater	09/27/93	09/09/94, 59 FR 46562.	
211.5710	Roll Coating	09/27/93	09/09/94, 59 FR 46562.	
211.5730	Roll Printer	09/27/93	09/09/94, 59 FR 46562.	
211.5750	Roll Printing	09/27/93	09/09/94, 59 FR 46562.	
211.5770	Rotogravure Printing	09/27/93	09/09/94, 59 FR 46562.	
211.5790	Rotogravure Printing Line	09/27/93	09/09/94, 59 FR 46562.	
211.5800	Rubber	09/14/10	03/23/12, 77 FR 16940.	
211.5810	Safety Relief Valve	09/27/93	09/09/94, 59 FR 46562.	
211.5830	Sandblasting	09/27/93	09/09/94, 59 FR 46562.	
211.5850	Sanding Sealers	09/27/93	09/09/94, 59 FR 46562.	
211.5860	Scientific Instrument	06/25/10	03/23/12, 77 FR 16940.	
211.5870	Screening	09/27/93	09/09/94, 59 FR 46562.	
211.5875	Screen Printing	06/25/10	03/23/12, 77 FR 16940.	
211.5885	Screen Reclamation	06/25/10	03/23/12, 77 FR 16940.	
211.5890	Sealer	09/14/10	03/23/12, 77 FR 16940.	
211.5910	Semi Transparent Stains	09/27/93	09/09/94, 59 FR 46562.	
211.5930	Sensor	09/27/93	09/09/94, 59 FR 46562.	
211.5950	Set of Safety Relief Valves	09/27/93	09/09/94, 59 FR 46562.	
211.5970	Sheet Basecoat	09/27/93	09/09/94, 59 FR 46562.	
211.5980	Sheet-Fed	05/09/95	11/08/95, 60 FR 56238.	
211.5985	Sheet Rubber Lining Installation	09/14/10	03/23/12, 77 FR 16940.	
211.5987	Shock-Free Coating	09/14/10	03/23/12, 77 FR 16940.	
211.5990	Shotblasting	09/27/93	09/09/94, 59 FR 46562.	
211.6010	Side Seam Spray Coat	09/27/93	09/09/94, 59 FR 46562.	
211.6012	Silicone-Release Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6015	Single-Ply Roof Membrane	09/14/10	03/23/12, 77 FR 16940.	
211.6017	Single-Ply Roof Membrane Adhesive Primer	09/14/10	03/23/12, 77 FR 16940.	
211.6020	Single-Ply Roof Membrane Installation and Repair Adhesive.	09/14/10	03/23/12, 77 FR 16940.	
211.6025	Single Unit Operation	05/22/95	04/02/96, 61 FR 14484.	
211.6030	Smoke	09/27/93	09/09/94, 59 FR 46562.	
211.6050	Smokeless Flare	09/27/93	09/09/94, 59 FR 46562.	
211.6060	Soft Coat	05/09/95	10/26/95, 60 FR 54807.	
211.6063	Solar-Absorbent Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6065	Solids Turnover Ratio (R_T)	09/14/10	03/23/12, 77 FR 16940.	
211.6070	Solvent	09/27/93	09/09/94, 59 FR 46562.	
211.6090	Solvent Cleaning	09/27/93	09/09/94, 59 FR 46562.	
211.6110	Solvent Recovery System	01/18/94	10/21/96, 61 FR 54556.	
211.6130	Source	04/17/01	11/08/01, 66 FR 56449.	
211.6140	Specialty Coatings	05/09/95	10/26/95, 60 FR 54807.	
211.6145	Specialty Coatings for Motor Vehicles	05/09/95	07/25/96, 61 FR 38577.	
211.6150	Specialty High Gloss Catalyzed Coating	09/27/93	09/09/94, 59 FR 46562.	
211.6170	Specialty Leather	01/18/94	10/21/96, 61 FR 54556.	
211.6190	Specialty Soybean Crushing Source	09/27/93	09/09/94, 59 FR 46562.	
211.6210	Splash Loading	09/27/93	09/09/94, 59 FR 46562.	
211.6230	Stack	09/27/93	09/09/94, 59 FR 46562.	
211.6250	Stain Coating	01/18/94	10/21/96, 61 FR 54556.	
211.6270	Standard Conditions	09/27/93	09/09/94, 59 FR 46562.	
211.6290	Standard Cubic Foot (Scf)	09/27/93	09/09/94, 59 FR 46562.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
211.6310	Start Up	09/27/93	09/09/94, 59 FR 46562.	
211.6330	Stationary Emission Source	09/27/93	09/09/94, 59 FR 46562.	
211.6350	Stationary Emission Unit	09/27/93	09/09/94, 59 FR 46562.	
211.6370	Stationary Source	09/27/93	09/09/94, 59 FR 46562.	
211.6390	Stationary Storage Tank	09/27/93	09/09/94, 59 FR 46562.	
211.6400	Stencil Coat	09/14/10	03/23/12, 77 FR 16940.	
211.6405	Sterilization Indicating Ink	06/25/10	03/23/12, 77 FR 16940.	
211.6410	Storage Tank or Storage Vessel	09/27/93	09/09/94, 59 FR 46562.	
211.6420	Strippable Spray Booth Coating	02/02/98	05/19/98, 63 FR 27489.	
211.6425	Stripping	06/25/10	03/23/12, 77 FR 16940.	
211.6427	Structural Glazing	09/14/10	03/23/12, 77 FR 16940.	
211.6430	Styrene Devolatilizer Unit	09/27/93	09/09/94, 59 FR 46562.	
211.6450	Styrene Recovery Unit	09/27/93	09/09/94, 59 FR 46562.	
211.6460	Subfloor	09/14/10	03/23/12, 77 FR 16940.	
211.6470	Submerged Loading Pipe	09/27/93	09/09/94, 59 FR 46562.	
211.6490	Substrate	09/27/93	09/09/94, 59 FR 46562.	
211.6510	Sulfuric Acid Mist	09/27/93	09/09/94, 59 FR 46562.	
211.6530	Surface Condenser	09/27/93	09/09/94, 59 FR 46562.	
211.6535	Surface Preparation	06/25/10	03/23/12, 77 FR 16940.	
211.6540	Surface Preparation Materials	05/09/95	07/25/96, 61 FR 38577.	
211.6550	Synthetic Organic Chemical or Polymer Manufacturing Plant.	09/27/93	09/09/94, 59 FR 46562.	
211.6570	Tablet Coating Operation	09/27/93	09/09/94, 59 FR 46562.	
211.6580	Texture Coat	05/09/95	10/26/95, 60 FR 54807.	
211.6585	Thin Metal Laminating Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.6587	Thin Particleboard	07/27/11	03/23/12, 77 FR 16940.	
211.6590	Thirty Day Rolling Average	09/27/93	09/09/94, 59 FR 46562.	
211.6610	Three Piece Can	09/27/93	09/09/94, 59 FR 46562.	
211.6620	Three or Four Stage Coating System	05/09/95	07/25/96, 61 FR 38577.	
211.6630	Through-the-Valve Fill	01/18/94	10/21/96, 61 FR 54556.	
211.6635	Tileboard	07/27/11	03/23/12, 77 FR 16940.	
211.6640	Tire Repair	09/14/10	03/23/12, 77 FR 16940.	
211.6650	Tooling Resin	01/18/94	10/21/96, 61 FR 54556.	
211.6670	Topcoat	09/14/10	03/23/12, 77 FR 16940.	
211.6690	Topcoat Operation	09/14/10	03/23/12, 77 FR 16940.	
211.6695	Topcoat System	05/09/95	07/25/96, 61 FR 38577.	
211.6710	Touch-Up	01/18/94	10/21/96, 61 FR 54556.	
211.6720	Touch-Up Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6730	Transfer Efficiency	09/27/93	09/09/94, 59 FR 46562.	
211.6740	Translucent Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6750	Tread End Cementing	09/27/93	09/09/94, 59 FR 46562.	
211.6770	True Vapor Pressure	09/27/93	09/09/94, 59 FR 46562.	
211.6780	Trunk Interior Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6790	Turnaround	09/27/93	09/09/94, 59 FR 46562.	
211.6810	Two Piece Can	09/27/93	09/09/94, 59 FR 46562.	
211.6825	Underbody Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6830	Under-the-Cup Fill	01/18/94	10/21/96, 61 FR 54556.	
211.6850	Undertread Cementing	09/27/93	09/09/94, 59 FR 46562.	
211.6860	Uniform Finish Blender	05/09/95	07/25/96, 61 FR 38577.	
211.6870	Unregulated Safety Relief Valve	09/27/93	09/09/94, 59 FR 46562.	
211.6880	Vacuum Metallizing	05/09/95	10/26/95, 60 FR 54807.	
211.6885	Vacuum Metalizing Coating	09/14/10	03/23/12, 77 FR 16940.	
211.6890	Vacuum Producing System	09/27/93	09/09/94, 59 FR 46562.	
211.6910	Vacuum Service	09/27/93	09/09/94, 59 FR 46562.	
211.6930	Valves Not Externally Regulated	09/27/93	09/09/94, 59 FR 46562.	
211.6950	Vapor Balance System	09/27/93	09/09/94, 59 FR 46562.	
211.6970	Vapor Collection System	10/25/94	04/03/95, 60 FR 16801.	
211.6990	Vapor Control System	10/25/94	04/03/95, 60 FR 16801.	
211.7010	Vapor Mounted Primary Seal	09/27/93	09/09/94, 59 FR 46562.	
211.7030	Vapor Recovery System	09/27/93	09/09/94, 59 FR 46562.	
211.7050	Vapor-Suppressed Polyester Resin	01/18/94	10/21/96, 61 FR 54556.	
211.7070	Vinyl Coating	09/27/93	09/09/94, 59 FR 46562.	
211.7090	Vinyl Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.7110	Volatile Organic Liquid (VOL)	09/27/93	09/09/94, 59 FR 46562.	
211.7130	Volatile Organic Material Content (VOMC)	09/27/93	09/09/94, 59 FR 46562.	
211.7150	Volatile Organic Material (VOM) or Volatile Organic Compound (VOC).	03/24/15	12/28/16, 81 FR 95475.	
211.7170	Volatile Petroleum Liquid	09/27/93	09/09/94, 59 FR 46562.	
211.7190	Wash Coat	09/27/93	09/09/94, 59 FR 46562.	
211.7200	Washoff Operations	02/02/98	05/19/98, 63 FR 27489.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
211.7210	Wastewater (Oil/Water) Separator	09/27/93	09/09/94, 59 FR 46562.	
211.7220	Waterproof Resorcinol Glue	09/14/10	03/23/12, 77 FR 16940.	
211.7230	Weak Nitric Acid Manufacturing Process	09/27/93	09/09/94, 59 FR 46562.	
211.7240	Weatherstrip Adhesive	09/14/10	03/23/12, 77 FR 16940.	
211.7250	Web	09/27/93	09/09/94, 59 FR 46562.	
211.7270	Wholesale Purchase Consumer	09/27/93	09/09/94, 59 FR 46562.	
211.7290	Wood Furniture	06/25/10	03/23/12, 77 FR 16940.	
211.7310	Wood Furniture Coating	09/27/93	09/09/94, 59 FR 46562.	
211.7330	Wood Furniture Coating Line	09/27/93	09/09/94, 59 FR 46562.	
211.7350	Woodworking	09/27/93	09/09/94, 59 FR 46562.	
Part 212: Visible and Particulate Matter Emissions				
Subpart A: General				
212.107	Measurement Method for Visible Emissions	05/22/96	03/11/98, 63 FR 11842.	
212.108	Measurement Methods for PM–10 Emissions and Condensible PM–10 Emissions.	05/22/96	03/11/98, 63 FR 11842.	
212.109	Measurement Methods for Opacity	05/22/96	03/11/98, 63 FR 11842.	
212.110	Measurement Methods for Particulate Matter	05/22/96	03/11/98, 63 FR 11842.	
212.111	Abbreviations and Units	10/04/91	10/21/93, 58 FR 54291.	
212.113	Incorporations by Reference	05/22/96	07/14/99, 64 FR 37847.	
Subpart B: Visible Emissions				
212.121	Opacity Standards	07/13/88	12/29/92, 57 FR 61834.	
212.122	Visible Emissions Limitations for Certain Emission Units for Which Construction or Modification Commenced on or After April 14, 1972.	07/13/88	12/29/92, 57 FR 61834.	
212.123	Visible Emissions Limitations for All Other Emission Units.	07/13/88	12/29/92, 57 FR 61834.	
212.124	Exceptions	07/13/88	12/29/92, 57 FR 61834.	
212.125	Determination of Violations	07/13/88	12/29/92, 57 FR 61834.	
212.126	Adjusted Opacity Standards Procedures	07/13/88	12/29/92, 57 FR 61834.	
Subpart D: Particulate Matter Emissions From Incinerators				
212.181	Limitations for Incinerators	06/04/80	11/27/81, 46 FR 57893.	
212.182	Aqueous Waste Incinerators	06/04/80	11/27/81, 46 FR 57893.	
212.183	Certain Wood Waste Incinerators	06/04/80	11/27/81, 46 FR 57893.	
212.184	Explosive Waste Incinerators	06/04/80	11/27/81, 46 FR 57893.	
212.185	Continuous Automatic Stoking Animal Pathological Waste Incinerators.	12/30/86	09/15/93, 58 FR 48312.	
Subpart E: Particulate Matter Emissions From Fuel Combustion Emission Units				
212.201	Emission Units for Which Construction or Modification Commenced Prior to April 14, 1972, Using Solid Fuel Exclusively Located in the Chicago Area.	07/09/86	12/29/92, 57 FR 61834.	
212.202	Emission Units for Which Construction or Modification Commenced Prior to April 14, 1972, Using Solid Fuel Exclusively Located Outside the Chicago Area.	07/09/86	12/29/92, 57 FR 61834.	
212.203	Controlled Emission Units for Which Construction or Modification Commenced Prior to April 14, 1972, Using Solid Fuel Exclusively.	07/09/86	12/29/92, 57 FR 61834.	
212.204	Emission Units for Which Construction or Modification Commenced on or After April 14, 1972, Using Solid Fuel Exclusively.	07/09/86	12/29/92, 57 FR 61834.	
212.205	Coal-Fired Industrial Boilers for Which Construction or Modification Commenced Prior to April 14, 1972, Equipped With Flue Gas Desulfurization Systems.	10/19/81	02/22/84, 49 FR 6490.	
212.206	Emission Units Using Liquid Fuel Exclusively	04/14/72	05/31/72, 37 FR 10842.	
212.207	Emission Units Using More Than One Type of Fuel.	04/14/72	05/31/72, 37 FR 10842.	

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212.208	Aggregation of Emission Units for Which Construction or Modification Commenced Prior to April 14, 1972.	04/14/72	05/31/72, 37 FR 10842.	
212.210	Emissions Limitations for Certain Fuel Combustion Emission Units Located in the Vicinity of Granite City.	05/22/96	07/14/99, 64 FR 37847.	
Subpart K: Fugitive Particulate Matter				
212.301	Fugitive Particulate Matter	10/26/79	02/21/80, 45 FR 11472.	
212.302	Geographical Areas of Application	05/22/96	07/14/99, 64 FR 37847.	
212.304	Storage Piles	10/26/79	04/26/82, 47 FR 17814.	
212.305	Conveyor Loading Operations	10/26/79	04/26/82, 47 FR 17814.	
212.306	Traffic Areas	10/26/79	02/21/80, 45 FR 11472.	
212.307	Materials Collected by Pollution Control Equipment.	10/26/79	02/21/80, 45 FR 11472.	
212.308	Spraying or Choke-Feeding Required	10/26/79	02/21/80, 45 FR 11472.	
212.309	Operating Program	05/22/96	07/14/99, 64 FR 37847.	
212.310	Minimum Operating Program	10/26/79	02/21/80, 45 FR 11472.	
212.312	Amendment to Operating Program	10/26/79	02/21/80, 45 FR 11472.	
212.313	Emission Standard for Particulate Collection Equipment.	10/26/79	02/21/80, 45 FR 11472.	
212.314	Exception for Excess Wind Speed	10/26/79	02/21/80, 45 FR 11472.	
212.315	Covering for Vehicles	10/26/79	02/21/80, 45 FR 11472.	
212.316	Emissions Limitations for Emission Units in Certain Areas.	05/22/96	07/14/99, 64 FR 37847.	
Subpart L: Particulate Matter Emissions From Process Emission Units				
212.321	Process Emission Units for Which Construction or Modification Commenced on or After April 14, 1972.	09/28/79	02/21/80, 45 FR 11472.	
212.322	Process Emission Units for Which Construction or Modification Commenced Prior to April 14, 1972.	09/28/79	02/21/80, 45 FR 11472.	
212.323	Stock Piles	09/28/79	02/21/80, 45 FR 11472.	
212.324	Process Emission Units in Certain Areas	05/22/96	03/11/98, 63 FR 11842.	
Subpart N: Food Manufacturing				
212.361	Corn Wet Milling Processes	09/28/79	02/21/80, 45 FR 11472.	
212.362	Emission Units in Certain Areas	05/22/96	03/11/98, 63 FR 11842.	
Subpart O: Petroleum Refining, Petrochemical and Chemical Manufacturing				
212.381	Catalyst Regenerators of Fluidized Catalytic Converters.	09/28/79	02/21/80, 45 FR 11472.	
Subpart Q: Stone, Clay, Glass and Concrete Manufacturing				
212.421	Portland Cement Processes for Which Construction or Modification Commenced on or After April 14, 1972.	04/14/72	05/31/72, 37 FR 10842.	
212.422	Portland Cement Manufacturing Processes	09/28/79	02/21/80, 45 FR 11472.	
212.423	Emission Limits for the Portland Cement Manufacturing Plant Located in LaSalle County, South of the Illinois River.	10/04/91	10/21/93, 58 FR 54291.	
212.424	Fugitive Particulate Matter Control for the Portland Cement Manufacturing Plant and Associated Quarry Operations Located in LaSalle County, South of the Illinois River.	05/15/92	01/12/93, 58 FR 3844.	
212.425	Emission Units in Certain Areas	05/22/96	03/11/98, 63 FR 11842.	
Subpart R: Primary and Fabricated Metal Products and Machinery Manufacture				
212.441	Steel Manufacturing Processes	09/28/79	02/21/80, 45 FR 11472.	
212.442	Beehive Coke Ovens	09/28/79	02/21/80, 45 FR 11472.	
212.443	Coke Plants	05/15/92	01/12/93, 58 FR 3844.	
212.444	Sinter Processes	09/28/79	09/03/81, 46 FR 44172.	
212.445	Blast Furnace Cast Houses	05/15/92	01/12/93, 58 FR 3844.	
212.446	Basic Oxygen Furnaces	05/22/96	03/11/98, 63 FR 11842.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
212.447	Hot Metal Desulfurization Not Located in the BOF.	09/28/79	09/03/81, 46 FR 44172.	
212.448	Electric Arc Furnaces	09/28/79	09/03/81, 46 FR 44172.	
212.449	Argon-Oxygen Decarburization Vessels	09/28/79	09/03/81, 46 FR 44172.	
212.450	Liquid Steel Charging	09/28/79	09/03/81, 46 FR 44172.	
212.451	Hot Scarfing Machines	09/28/79	09/03/81, 46 FR 44172.	
212.455	Highlines on Steel Mills	10/26/79	02/21/80, 45 FR 11472.	
212.456	Certain Small Foundries	09/28/79	02/21/80, 45 FR 11472.	
212.457	Certain Small Iron-Melting Air Furnaces	09/28/79	07/12/82, 47 FR 30057.	
212.458	Emission Units in Certain Areas	05/22/96	03/11/98, 63 FR 11842.	
Subpart S: Agriculture				
212.461	Grain-Handling and Drying in General	09/28/79	02/21/80, 45 FR 11472.	
212.462	Grain-Handling Operations	09/28/79	02/21/80, 45 FR 11472.	
212.463	Grain Drying Operations	09/28/79	02/21/80, 45 FR 11472.	
212.464	Sources in Certain Areas	05/22/96	03/11/98, 63 FR 11842.	
Subpart T: Construction and Wood Products				
212.681	Grinding, Woodworking, Sandblasting and Shotblasting.	04/14/72	05/31/72, 37 FR 10842.	
Subpart U: Additional Control Measures				
212.700	Applicability	07/11/94	07/13/95, 60 FR 36060.	
212.701	Contingency Measure Plans, Submittal and Compliance Date.	07/11/94	07/13/95, 60 FR 36060.	
212.702	Determination of Contributing Sources	07/11/94	07/13/95, 60 FR 36060.	
212.703	Contingency Measure Plan Elements	07/11/94	07/13/95, 60 FR 36060.	
212.704	Implementation	07/11/94	07/13/95, 60 FR 36060.	
212.705	Alternative Implementation	07/11/94	07/13/95, 60 FR 36060.	
212.Appendix C:	Past Compliance Dates	04/14/72	05/31/72, 37 FR 10842	Approved as Rules 202(e), 203(c), 203(d)(3)(A) & (B), 203(d)(5)(L) & (M), 203(d)(8)(J), 203(f)(3) Preamble, 203(f)(3)(F) Preamble, and 203(i).
Part 214: Sulfur Limitations				
Subpart A: General Provisions				
214.101	Measurement Methods	01/15/91	06/26/92, 57 FR 28617.	
214.102	Abbreviations and Units	12/05/88	01/28/94, 59 FR 4001.	
214.104	Incorporations by Reference	01/15/91	01/28/94, 59 FR 4001.	
Subpart B: New Fuel Combustion Emission Sources				
214.121	Large Sources	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(a).
214.122	Small Sources	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(b).
Subpart C: Existing Solid Fuel Combustion Emission Sources				
214.141	Sources Located in Metropolitan Areas	03/28/83	09/03/92, 57 FR 40333	thru (a).
214.141	Sources Located in Metropolitan Areas	05/20/86	09/02/92, 57 FR 40126	(b), (c), and (d).
214.142	Small Sources Located Outside Metropolitan Areas.	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(c)(1)(B).
214.143	Large Sources Located Outside Metropolitan Areas.	02/03/79	02/21/80, 45 FR 11472.	
Subpart D: Existing Liquid or Mixed Fuel Combustion Emission Sources				
214.161	Liquid Fuel Burned Exclusively	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(c)(2).
214.162	Combination of Fuels	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(d).
Subpart E: Aggregation of Sources Outside Metropolitan Areas				
214.181	Dispersion Enhancement Techniques	02/03/79	02/21/80, 45 FR 11472.	
214.182	Prohibition	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(e) (intro).
214.183	General Formula	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(e)(1).

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214.184	Special Formula	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(e)(2).
214.185	Alternative Emission Rate	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(e)(3).
214.186	New Operating Permits	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(e)(4).
Subpart F: Alternative Standards for Sources Inside Metropolitan Areas				
214.201	Alternative Standards for Sources in Metropolitan Areas.	03/28/83	09/03/92, 57 FR 40333.	
214.202	Dispersion Enhancement Techniques	03/28/83	09/03/92, 57 FR 40333.	
Subpart K: Process Emission Sources				
214.301	General Limitation	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(f)(1)(A).
214.302	Exception for Air Pollution Control Equipment	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(f)(1)(C).
214.303	Use of Sulfuric Acid	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(f)(2)(B).
Subpart O: Petroleum Refining, Petrochemical and Chemical Manufacturing				
214.381	Sulfuric Acid Manufacturing	02/03/79	02/21/80, 45 FR 11472	Only (a) and (b). Approved as Rule 204(f)(1)(B) and (f)(2)(A).
214.382	Petroleum and Petrochemical Processes	12/05/88	01/28/94, 59 FR 4001.	
214.383	Chemical Manufacturing	02/03/79	02/21/80, 45 FR 11472	Approved as Rule 204(f)(1)(E).
Subpart X: Utilities				
214.560	Scope	05/20/86	09/02/92, 57 FR 40126.	
214.561	E. D. Edwards Electric Generating Station	07/11/03	11/10/08, 73 FR 66555.	
214.Appendix C:	Compliance Dates	04/14/72	05/31/72, 37 FR 10842	Approved as Rule 204(e)(1).
Part 215: Organic Material Emission Standards and Limitations				
Subpart A: General Provisions				
215.101	Clean-Up and Disposal Operations	07/28/79	02/21/80, 45 FR 11472.	
215.102	Testing Methods	05/14/91	08/18/92, 57 FR 37100.	
215.104	Definitions	01/28/13	10/06/14, 79 FR 60070.	
215.105	Incorporation by Reference	01/28/13	10/06/14, 79 FR 60070.	
215.108	Measurement of Vapor Pressures	05/14/91	08/18/92, 57 FR 37100.	
215.109	Monitoring for Negligibly-Reactive Compounds.	06/19/98	01/15/99, 64 FR 2581.	
Subpart B: Organic Emissions From Storage and Loading Operations				
215.121	Storage Containers	07/28/79	02/21/80, 45 FR 11472.	
215.122	Loading Operations	07/28/79	02/21/80, 45 FR 11472.	
215.123	Petroleum Liquid Storage Tanks	07/28/79	02/21/80, 45 FR 11472.	
215.124	External Floating Roofs	01/21/83	06/29/90, 55 FR 26814.	
215.125	Compliance Dates and Geographical Areas	01/21/83	06/29/90, 55 FR 26814.	
215.126	Compliance Plan	01/21/83	06/29/90, 55 FR 26814.	
Subpart C: Organic Emissions From Miscellaneous Equipment				
215.141	Separation Operations	07/28/79	02/21/80, 45 FR 11472.	
215.142	Pumps and Compressors	07/28/79	02/21/80, 45 FR 11472.	
215.143	Vapor Blowdown	07/28/79	02/21/80, 45 FR 11472.	
215.144	Safety Relief Valves	07/28/79	02/21/80, 45 FR 11472.	
Subpart E: Solvent Cleaning				
215.181	Solvent Cleaning in General	07/28/79	02/21/80, 45 FR 11472.	
215.182	Cold Cleaning	07/28/79	02/21/80, 45 FR 11472.	
215.183	Open Top Vapor Degreasing	07/28/79	02/21/80, 45 FR 11472.	
215.184	Conveyorized Degreasing	07/28/79	02/21/80, 45 FR 11472.	
Subpart F: Coating Operations				
215.202	Compliance Schedules	07/28/79	02/21/80, 45 FR 11472.	
215.204	Emission Limitations for Manufacturing Plants	06/19/98	01/15/99, 64 FR 2581.	
215.205	Alternative Emission Limitations	06/19/98	01/15/99, 64 FR 2581.	
215.206	Exemptions From Emission Limitations	06/19/98	01/15/99, 64 FR 2581.	
215.207	Compliance by Aggregation of Emission Units	06/19/98	01/15/99, 64 FR 2581.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
215.208	Testing Methods for Volatile Organic Material Content.	07/28/79	02/21/80, 45 FR 11472.	
215.209	Exemption From General Rule on Use of Organic Material.	07/28/79	02/21/80, 45 FR 11472.	
215.211	Compliance Dates and Geographical Areas	06/19/98	01/15/99, 64 FR 2581.	
215.212	Compliance Plan	06/19/98	01/15/99, 64 FR 2581.	
215.213	Special Requirements for Compliance Plan	07/28/79	02/21/80, 45 FR 11472.	
215.215	DMI Emissions Limitations	07/28/79	02/21/80, 45 FR 11472.	
Subpart H: Special Limitations for Sources in Major Urbanized Areas Which Are Nonattainment for Ozone				
215.240	Applicability	06/29/87	06/29/90, 55 FR 26814.	
215.241	External Floating Roofs	06/29/87	06/29/90, 55 FR 26814.	
215.249	Compliance Dates	06/29/87	06/29/90, 55 FR 26814.	
Subpart K: Use of Organic Material				
215.301	Use of Organic Material	07/28/79	02/21/80, 45 FR 11472.	
215.302	Alternative Standard	07/28/79	02/21/80, 45 FR 11472.	
215.303	Fuel Combustion Emission Sources	07/28/79	02/21/80, 45 FR 11472.	
215.304	Operations With Compliance Program	07/28/79	02/21/80, 45 FR 11472.	
Subpart P: Printing and Publishing				
215.408	Heatset Web Offset Lithographic Printing	09/30/87	06/29/90, 55 FR 26814.	
Subpart Q: Leaks From Synthetic Organic Chemical and Polymer Manufacturing Equipment				
215.420	Applicability	12/14/87	06/29/90, 55 FR 26814.	
215.421	General Requirements	12/14/87	06/29/90, 55 FR 26814.	
215.422	Inspection Program Plan for Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.423	Inspection Program for Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.424	Repairing Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.425	Recordkeeping for Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.426	Reporting for Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.427	Alternative Program for Leaks	08/28/85	06/29/90, 55 FR 26814.	
215.428	Compliance Dates	12/14/87	06/29/90, 55 FR 26814.	
215.429	Compliance Plan	12/14/87	06/29/90, 55 FR 26814.	
215.430	General Requirements	12/14/87	06/29/90, 55 FR 26814.	
215.431	Inspection Program Plan for Leaks	12/14/87	06/29/90, 55 FR 26814.	
215.433	Repairing Leaks	12/14/87	06/29/90, 55 FR 26814.	
215.434	Recordkeeping for Leaks	12/14/87	06/29/90, 55 FR 26814.	
215.435	Report for Leaks	12/14/87	06/29/90, 55 FR 26814.	
215.437	Open-Ended Valves	12/14/87	06/29/90, 55 FR 26814.	
215.438	Compliance Plan	12/14/87	06/29/90, 55 FR 26814.	
Subpart R: Petroleum Refining and Related Industries; Asphalt Materials				
215.441	Petroleum Refinery Waste Gas Disposal	07/28/79	02/21/80, 45 FR 11472.	
215.442	Vacuum Producing Systems	07/28/79	02/21/80, 45 FR 11472.	
215.443	Wastewater (Oil/Water) Separator	07/28/79	02/21/80, 45 FR 11472.	
215.444	Process Unit Turnarounds	07/28/79	02/21/80, 45 FR 11472.	
215.445	Leaks: General Requirements	01/21/83	11/27/87, 52 FR 45333.	
215.446	Monitoring Program Plan for Leaks	01/21/83	11/27/87, 52 FR 45333.	
215.447	Monitoring Program for Leaks	01/21/83	11/27/87, 52 FR 45333.	
215.448	Recordkeeping for Leaks	01/21/83	11/27/87, 52 FR 45333.	
215.449	Reporting for Leaks	01/21/83	11/27/87, 52 FR 45333.	
215.450	Alternative Program for Leaks	01/21/83	11/27/87, 52 FR 45333.	
215.451	Sealing Device Requirements	01/21/83	11/27/87, 52 FR 45333.	
215.453	Compliance Dates and Geographical Areas	01/21/83	06/29/90, 55 FR 26814.	
Subpart S: Rubber and Miscellaneous Plastic Products				
215.461	Manufacture of Pneumatic Rubber Tires	01/21/83	11/27/87, 52 FR 45333.	
215.462	Green Tire Spraying Operations	01/21/83	11/27/87, 52 FR 45333.	
215.463	Alternative Emission Reduction Systems	01/21/83	11/27/87, 52 FR 45333.	
215.464	Emissions Testing	01/21/83	11/27/87, 52 FR 45333.	
215.465	Compliance Dates and Geographical Areas	01/21/83	06/29/90, 55 FR 26814.	
215.466	Compliance Plan	01/21/83	06/29/90, 55 FR 26814.	

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	Subpart T: Pharmaceutical Manufacturing			
215.480	Applicability of Subpart T	05/14/91	08/18/92, 57 FR 37100.	
215.481	Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers.	05/14/91	08/18/92, 57 FR 37100.	
215.482	Control of Air Dryers, Production Equipment Exhaust Systems and Filters.	05/14/91	08/18/92, 57 FR 37100.	
215.483	Material Storage and Transfer	05/14/91	08/18/92, 57 FR 37100.	
215.484	In-Process Tanks	05/14/91	08/18/92, 57 FR 37100.	
215.485	Leaks	05/14/91	08/18/92, 57 FR 37100.	
215.486	Other Emission Sources	05/14/91	08/18/92, 57 FR 37100.	
215.487	Testing	05/14/91	08/18/92, 57 FR 37100.	
215.488	Monitors for Air Pollution Control Equipment	05/14/91	08/18/92, 57 FR 37100.	
215.489	Recordkeeping (Renumbered)	05/14/91	08/18/92, 57 FR 37100.	
215.490	Compliance Schedule (Renumbered)	05/14/91	08/18/92, 57 FR 37100.	
	Subpart V: Air Oxidation Processes			
215.520	Applicability	12/14/87	06/29/90, 55 FR 26814.	
215.521	Definitions	12/14/87	06/29/90, 55 FR 26814.	
215.525	Emission Limitations for Air Oxidation Processes.	12/14/87	06/29/90, 55 FR 26814.	
215.526	Testing and Monitoring	12/14/87	06/29/90, 55 FR 26814.	
215.527	Compliance Date	12/14/87	06/29/90, 55 FR 26814.	
	Subpart W: Agriculture			
215.541	Pesticide Exception	07/28/79	02/21/80, 45 FR 11472.	
	Subpart X: Construction			
215.561	Architectural Coatings	07/28/79	02/21/80, 45 FR 11472.	
215.562	Paving Operations	07/28/79	02/21/80, 45 FR 11472.	
215.563	Cutback Asphalt	07/28/79	02/21/80, 45 FR 11472.	
	Subpart Y: Gasoline Distribution			
215.581	Bulk Gasoline Plants	07/28/79	02/21/80, 45 FR 11472.	
215.582	Bulk Gasoline Terminals	06/29/87	06/29/90, 55 FR 26814.	
215.583	Gasoline Dispensing Facilities—Storage Tank Filling Operations.	06/29/87	06/29/90, 55 FR 26814.	
215.584	Gasoline Delivery Vessels	06/29/87	06/29/90, 55 FR 26814.	
	Subpart Z: Dry Cleaners			
215.607	Standards for Petroleum Solvent Dry Cleaners.	04/03/87	06/29/90, 55 FR 26814.	
215.608	Operating Practices for Petroleum Solvent Dry Cleaners.	04/03/87	06/29/90, 55 FR 26814.	
215.609	Program for Inspection and Repair of Leaks	04/03/87	06/29/90, 55 FR 26814.	
215.610	Testing and Monitoring	04/03/87	06/29/90, 55 FR 26814.	
215.611	Exemption for Petroleum Solvent Dry Cleaners.	04/03/87	06/29/90, 55 FR 26814.	
215.612	Compliance Dates and Geographical Areas	04/03/87	06/29/90, 55 FR 26814.	
215.613	Compliance Plan	04/03/87	06/29/90, 55 FR 26814.	
	Subpart BB: Polystyrene Plants			
215.875	Applicability of Subpart BB	09/30/87	06/29/90, 55 FR 26814.	
215.877	Emissions Limitation at Polystyrene Plants	09/30/87	06/29/90, 55 FR 26814.	
215.879	Compliance Date	09/30/87	06/29/90, 55 FR 26814.	
215.881	Compliance Plan	09/30/87	06/29/90, 55 FR 26814.	
215.883	Special Requirements for Compliance Plan	09/30/87	06/29/90, 55 FR 26814.	
215.886	Emissions Testing	09/30/87	06/29/90, 55 FR 26814.	
215.Appendix C:	Past Compliance Dates	07/28/79	02/21/80, 45 FR 11472	Approved as Rules 104(a), 104(g), 104(h), 205(j), and 205(m).

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
Part 216: Carbon Monoxide Emissions				
Subpart A: General Provisions				
216.101	Measurement Methods	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(f).
Subpart B: Fuel Combustion Emission Sources				
216.121	Fuel Combustion Emission Sources	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(a).
Subpart C: Incinerators				
216.141	Incinerators	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(b).
216.142	Exceptions	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(b)(1,2).
Subpart N: Petroleum Refining and Chemical Manufacture				
216.361	Petroleum and Petrochemical Processes	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(c).
216.362	Polybasic Organic Acid Partial Oxidation Manufacturing Processes.	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(h).
Subpart O: Primary and Fabricated Metal Products				
216.381	Cupolas	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(e).
216.382	Exception, General Motor's Ferrous Foundry in Vermilion County.	11/13/92	08/04/94, 59 FR 39686	
216.Appendix C:	Compliance Dates	07/28/79	02/21/80, 45 FR 11472	Approved as Rule 206(g).
Part 217: Nitrogen Oxides Emissions				
Subpart A: General Provisions				
217.101	Measurement Methods	09/25/07	06/26/09, 74 FR 30466.	
217.102	Abbreviations and Units	09/25/07	06/26/09, 74 FR 30466.	
217.104	Incorporations by Reference	09/25/07	06/26/09, 74 FR 30466.	
Subpart B: New Fuel Combustion Emission Sources				
217.121	New Emission Sources	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 207(a)(1)–(4), 207(a)(5)(A).
Subpart C: Existing Fuel Combustion Emission Sources				
217.141	Existing Emission Sources in Major Metropolitan Areas.	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 207(b) and (c).
Subpart K: Process Emission Sources				
217.301	Industrial Processes	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 207(e).
Subpart O: Chemical Manufacture				
217.381	Nitric Acid Manufacturing Processes	04/14/72	05/31/72, 37 FR 10862	Approved as Rule 207(d).
Subpart Q: Stationary Reciprocating Internal Combustion Engines and Turbines				
217.386	Applicability	09/25/07	06/26/09, 74 FR 30466.	
217.388	Control and Maintenance Requirements	09/25/07	06/26/09, 74 FR 30466.	
217.390	Emissions Averaging Plans	09/25/07	06/26/09, 74 FR 30466.	
217.392	Compliance	09/25/07	06/26/09, 74 FR 30466.	
217.394	Testing and Monitoring	09/25/07	06/26/09, 74 FR 30466.	
217.396	Recordkeeping and Reporting	09/25/07	06/26/09, 74 FR 30466.	
Subpart T: Cement Kilns				
217.400	Applicability	03/15/01	11/08/01, 66 FR 56449.	
217.402	Control Requirements	03/15/01	11/08/01, 66 FR 56449.	
217.404	Testing	03/15/01	11/08/01, 66 FR 56449.	
217.406	Monitoring	03/15/01	11/08/01, 66 FR 56449.	
217.408	Reporting	03/15/01	11/08/01, 66 FR 56449.	
217.410	Recordkeeping	03/15/01	11/08/01, 66 FR 56449.	

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Subpart U: NO_X Control and Trading Program for Specified NO_X Generating Units				
217.450	Purpose	04/17/01	11/08/01, 66 FR 56449.	
217.452	Severability	04/17/01	11/08/01, 66 FR 56449.	
217.454	Applicability	04/17/01	11/08/01, 66 FR 56449.	
217.456	Compliance Requirements	04/17/01	11/08/01, 66 FR 56449.	
217.458	Permitting Requirements	04/17/01	11/08/01, 66 FR 56449.	
217.460	Subpart U NO_X Trading Budget	04/17/01	11/08/01, 66 FR 56449.	
217.462	Methodology for Obtaining NO_X Allocations	04/17/01	11/08/01, 66 FR 56449.	
217.464	Methodology for Determining NO_X Allowances From the New Source Set-Aside.	04/17/01	11/08/01, 66 FR 56449.	
217.466	NO_X Allocations Procedure for Subpart U Budget Units.	04/17/01	11/08/01, 66 FR 56449.	
217.468	New Source Set-Asides for "New" Budget Units.	04/17/01	11/08/01, 66 FR 56449.	
217.470	Early Reduction Credits (ERCS) for Budget Units.	04/17/01	11/08/01, 66 FR 56449.	
217.472	Low-Emitter Requirements	04/17/01	11/08/01, 66 FR 56449.	
217.474	Opt-In Units	04/17/01	11/08/01, 66 FR 56449.	
217.476	Opt-In Process	04/17/01	11/08/01, 66 FR 56449.	
217.478	Opt-In Budget Units: Withdrawal From NO_X Trading Program.	04/17/01	11/08/01, 66 FR 56449.	
217.480	Opt-In Units: Change in Regulatory Status	04/17/01	11/08/01, 66 FR 56449.	
217.482	Allowance Allocations To Opt-In Budget Units	04/17/01	11/08/01, 66 FR 56449.	
Subpart V: Electric Power Generation				
217.521	Lake of Egypt Power Plant	04/13/78	06/18/01, 66 FR 32769.	
217.700	Purpose	04/17/01	06/18/01, 66 FR 32769.	
217.702	Severability	04/17/01	06/18/01, 66 FR 32769.	
217.704	Applicability	04/17/01	06/18/01, 66 FR 32769.	
217.706	Emission Limitations	04/17/01	06/18/01, 66 FR 32769.	
217.708	NO_X Averaging	04/17/01	06/18/01, 66 FR 32769.	
217.710	Monitoring	04/17/01	06/18/01, 66 FR 32769.	
217.712	Reporting and Recordkeeping	04/17/01	06/18/01, 66 FR 32769.	
Subpart W: NO_X Trading Program for Electrical Generating Units				
217.750	Purpose	12/26/00	11/08/01, 66 FR 56454.	
217.751	Sunset Provisions	11/02/09	03/01/10, 75 FR 9103.	
217.752	Severability	12/26/00	11/08/01, 66 FR 56454.	
217.754	Applicability	12/26/00	11/08/01, 66 FR 56454.	
217.756	Compliance Requirements	12/26/00	11/08/01, 66 FR 56454	Except (d)(3).
217.758	Permitting Requirements	12/26/00	11/08/01, 66 FR 56454.	
217.760	NOx Trading Budget	12/26/00	11/08/01, 66 FR 56454.	
217.762	Methodology for Calculating NO_X Allocations for Budget Electrical Generating Units (EGUs).	12/26/00	11/08/01, 66 FR 56454.	
217.764	NO_X Allocations for Budget EGUs	12/26/00	11/08/01, 66 FR 56454.	
217.768	New Source Set-Asides for "New" Budget EGUs.	12/26/00	11/08/01, 66 FR 56454.	
217.770	Early Reduction Credits for Budget EGUs	12/26/00	11/08/01, 66 FR 56454.	
217.774	Opt-In Units	12/26/00	11/08/01, 66 FR 56454.	
217.776	Opt-In Process	12/26/00	11/08/01, 66 FR 56454.	
217.778	Budget Opt-In Units: Withdrawal From NO_X Trading Program.	12/26/00	11/08/01, 66 FR 56454.	
217.780	Opt-In Units: Change in Regulatory Status	12/26/00	11/08/01, 66 FR 56454.	
217.782	Allowance Allocations to Budget Opt-In Units	12/26/00	11/08/01, 66 FR 56454.	
217.Appendix C:	Compliance Dates	04/14/72	05/31/72, 37 FR 10862.	
217.Appendix G:	Existing Reciprocating Internal Combustion Engines Affected by the NO_X Sip Call.	09/25/07	06/26/09, 74 FR 30466.	
Part 218: Organic Material Emission Standards and Limitations for the Chicago Area				
Subpart A: General Provisions				
218.100	Introduction	09/27/93	09/09/94, 59 FR 46562.	
218.101	Savings Clause	10/25/94	04/03/95, 60 FR 16801.	
218.102	Abbreviations and Conversion Factors	09/27/93	09/09/94, 59 FR 46562.	
218.103	Applicability	09/27/93	09/09/94, 59 FR 46562.	
218.104	Definitions	09/27/93	09/09/94, 59 FR 46562.	

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218.105	Test Methods and Procedures	07/27/11	03/23/12, 77 FR 16940.	
218.106	Compliance Dates	09/14/10	03/23/12, 77 FR 16940.	
218.107	Operation of Afterburners	09/27/93	09/09/94, 59 FR 46562.	
218.108	Exemptions, Variations, and Alternative Means of Control or Compliance Determinations.	01/24/94	10/21/96, 61 FR 54556.	
218.109	Vapor Pressure of Volatile Organic Liquids	09/27/93	09/09/94, 59 FR 46562.	
218.110	Vapor Pressure of Organic Material or Solvent.	09/27/93	09/09/94, 59 FR 46562.	
218.111	Vapor Pressure of Volatile Organic Material	09/27/93	09/09/94, 59 FR 46562.	
218.112	Incorporations by Reference	12/23/13	03/13/15, 80 FR 13248.	
218.114	Compliance With Permit Conditions	01/24/94	10/21/96, 61 FR 54556.	
Subpart B: Organic Emissions From Storage and Loading Operations				
218.119	Applicability for VOL	11/15/94	08/08/96, 61 FR 41338.	
218.120	Control Requirements for Storage Containers of VOL.	11/15/94	08/08/96, 61 FR 41338.	
218.121	Storage Containers	09/27/93	09/09/94, 59 FR 46562.	
218.122	Loading Operations	09/27/93	09/09/94, 59 FR 46562.	
218.123	Petroleum Liquid Storage Tanks	09/27/93	09/09/94, 59 FR 46562.	
218.124	External Floating Roofs	09/27/93	09/09/94, 59 FR 46562.	
218.125	Compliance Dates	11/15/94	08/08/96, 61 FR 41338.	
218.127	Testing VOL Operations	11/15/94	08/08/96, 61 FR 41338.	
218.128	Monitoring VOL Operations	01/28/13	10/06/14, 79 FR 60070.	
218.129	Recordkeeping and Reporting for VOL Operations.	11/15/94	08/08/96, 61 FR 41338.	
Subpart C: Organic Emissions From Miscellaneous Equipment				
218.141	Separation Operations	09/27/93	09/09/94, 59 FR 46562.	
218.142	Pumps and Compressors	08/16/91	09/09/94, 59 FR 46562.	
218.143	Vapor Blowdown	09/27/93	09/09/94, 59 FR 46562.	
218.144	Safety Relief Valves	09/27/93	09/09/94, 59 FR 46562.	
Subpart E: Solvent Cleaning				
218.181	Solvent Cleaning Degreasing Operations	06/25/10	03/23/12, 77 FR 16940.	
218.182	Cold Cleaning	06/09/97	11/26/97, 62 FR 62951.	
218.183	Open Top Vapor Degreasing	09/27/93	09/09/94, 59 FR 46562.	
218.184	Conveyorized Degreasing	09/27/93	09/09/94, 59 FR 46562.	
218.186	Test Methods	09/27/93	09/09/94, 59 FR 46562.	
218.187	Other Industrial Solvent Cleaning Operations	07/27/11	03/23/12, 77 FR 16940.	
Subpart F: Coating Operations				
218.204	Emission Limitations	07/27/11	03/23/12, 77 FR 16940.	
218.205	Daily-Weighted Average Limitations	09/14/10	03/23/12, 77 FR 16940.	
218.206	Solids Basis Calculation	09/27/93	09/09/94, 59 FR 46562.	
218.207	Alternative Emission Limitations	07/27/11	03/23/12, 77 FR 16940.	
218.208	Exemptions From Emission Limitations	10/25/11	04/19/13, 78 FR 23495.	
218.209	Exemption From General Rule on Use of Organic Material.	09/27/93	09/09/94, 59 FR 46562.	
218.210	Compliance Schedule	06/25/10	03/23/12, 77 FR 16940.	
218.211	Recordkeeping and Reporting	07/27/11	03/23/12, 77 FR 16940.	
218.212	Cross-Line Averaging To Establish Compliance for Coating Lines.	09/14/10	03/23/12, 77 FR 16940.	
218.213	Recordkeeping and Reporting for Cross-Line Averaging Participating Coating Lines.	05/09/95	02/13/96, 61 FR 5511.	
218.214	Changing Compliance Methods	05/09/95	02/13/96, 61 FR 5511.	
218.215	Wood Furniture Coating Averaging Approach	02/02/98	05/19/98, 63 FR 27489.	
218.216	Wood Furniture Coating Add-On Control Use	02/02/98	05/19/98, 63 FR 27489.	
218.217	Wood Furniture Coating and Flat Wood Paneling Coating Work Practice Standards.	07/27/11	03/23/12, 77 FR 16940.	
218.218	Work Practice Standards for Paper Coatings, Metal Furniture Coatings, and Large Appliance Coatings.	03/23/10	03/23/12, 77 FR 16940.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
218.219	Work Practice Standards for Automobile and Light-Duty Truck Assembly Coatings and Miscellaneous Metal and Plastic Parts Coatings.	09/14/10	03/23/12, 77 FR 16940.	
Subpart G: Use of Organic Material				
218.301	Use of Organic Material	09/27/93	09/09/94, 59 FR 46562.	
218.302	Alternative Standard	09/27/93	09/09/94, 59 FR 46562.	
218.303	Fuel Combustion Emission Units	09/27/93	09/09/94, 59 FR 46562.	
218.304	Operations With Compliance Program	09/27/93	09/09/94, 59 FR 46562.	
Subpart H: Printing and Publishing				
218.401	Flexographic and Rotogravure Printing	07/27/11	03/23/12, 77 FR 16940.	
218.402	Applicability	07/27/11	03/23/12, 77 FR 16940.	
218.403	Compliance Schedule	06/25/10	03/23/12, 77 FR 16940.	
218.404	Recordkeeping and Reporting	07/27/11	03/23/12, 77 FR 16940.	
218.405	Lithographic Printing: Applicability	06/25/10	03/23/12, 77 FR 16940.	
218.407	Emission Limitations and Control Requirements for Lithographic Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
218.409	Testing for Lithographic Printing on and After March 15, 1996.	07/27/11	03/23/12, 77 FR 16940.	
218.410	Monitoring Requirements for Lithographic Printing.	06/25/10	03/23/12, 77 FR 16940.	
218.411	Recordkeeping and Reporting for Lithographic Printing.	07/27/11	03/23/12, 77 FR 16940.	
218.412	Letterpress Printing Lines: Applicability	06/25/10	03/23/12, 77 FR 16940.	
218.413	Emission Limitations and Control Requirements for Letterpress Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
218.415	Testing for Letterpress Printing Lines	07/27/11	03/23/12, 77 FR 16940.	
218.416	Monitoring Requirements for Letterpress Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
218.417	Recordkeeping and Reporting for Letterpress Printing Lines.	07/27/11	03/23/12, 77 FR 16940.	
Subpart Q: Synthetic Organic Chemical and Polymer Manufacturing Plant				
218.421	General Requirements	09/27/93	09/09/94, 59 FR 46562.	
218.422	Inspection Program Plan for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.423	Inspection Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.424	Repairing Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.425	Recordkeeping for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.426	Report for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.427	Alternative Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.428	Open-Ended Valves	09/27/93	09/09/94, 59 FR 46562.	
218.429	Standards for Control Devices	09/27/93	09/09/94, 59 FR 46562.	
218.431	Applicability	05/09/95	03/23/98, 63 FR 13784.	
218.432	Control Requirements	05/09/95	03/23/98, 63 FR 13784.	
218.433	Performance and Testing Requirements	05/09/95	03/23/98, 63 FR 13784.	
218.434	Monitoring Requirements	05/09/95	03/23/98, 63 FR 13784.	
218.435	Recordkeeping and Reporting Requirements	05/09/95	03/23/98, 63 FR 13784.	
218.436	Compliance Date	05/09/95	03/23/98, 63 FR 13784.	
Subpart R: Petroleum Refining and Related Industries; Asphalt Materials				
218.441	Petroleum Refinery Waste Gas Disposal	09/27/93	09/09/94, 59 FR 46562.	
218.442	Vacuum Producing Systems	08/16/91	09/09/94, 59 FR 46562.	
218.443	Wastewater (Oil/Water) Separator	09/27/93	09/09/94, 59 FR 46562.	
218.444	Process Unit Turnarounds	08/16/91	09/09/94, 59 FR 46562.	
218.445	Leaks: General Requirements	09/27/93	09/09/94, 59 FR 46562.	
218.446	Monitoring Program Plan for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.447	Monitoring Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.448	Recordkeeping for Leaks	08/16/91	09/09/94, 59 FR 46562.	
218.449	Reporting for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.450	Alternative Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.451	Sealing Device Requirements	08/16/91	09/09/94, 59 FR 46562.	
218.452	Compliance Schedule for Leaks	09/27/93	09/09/94, 59 FR 46562.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
	Subpart S: Rubber and Miscellaneous Plastic Products			
218.461	Manufacture of Pneumatic Rubber Tires	09/27/93	09/09/94, 59 FR 46562.	
218.462	Green Tire Spraying Operations	09/27/93	09/09/94, 59 FR 46562.	
218.463	Alternative Emission Reduction Systems	09/27/93	09/09/94, 59 FR 46562.	
218.464	Emission Testing	09/27/93	09/09/94, 59 FR 46562.	
	Subpart T: Pharmaceutical Manufacturing			
218.480	Applicability	08/26/08	11/03/10, 75 FR 67623.	
218.481	Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers.	09/27/93	09/09/94, 59 FR 46562.	
218.482	Control of Air Dryers, Production Equipment Exhaust Systems and Filters.	09/27/93	09/09/94, 59 FR 46562.	
218.483	Material Storage and Transfer	09/27/93	09/09/94, 59 FR 46562.	
218.484	In-Process Tanks	08/16/91	09/09/94, 59 FR 46562.	
218.485	Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.486	Other Emission Units	09/27/93	09/09/94, 59 FR 46562.	
218.487	Testing	09/27/93	09/09/94, 59 FR 46562.	
218.488	Monitoring for Air Pollution Control Equipment	08/16/91	09/09/94, 59 FR 46562.	
218.489	Recordkeeping for Air Pollution Control Equipment.	09/27/93	09/09/94, 59 FR 46562.	
	Subpart V: Batch Operations and Air Oxidation Processes			
218.500	Applicability for Batch Operations	05/22/95	04/02/96, 61 FR 14484.	
218.501	Control Requirements for Batch Operations	05/22/95	04/02/96, 61 FR 14484.	
218.502	Determination of Uncontrolled Total Annual Mass Emissions and Average Flow Rate Values for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
218.503	Performance and Testing Requirements for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
218.504	Monitoring Requirements for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
218.505	Reporting and Recordkeeping for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
218.506	Compliance Date	05/22/95	04/02/96, 61 FR 14484.	
218.520	Emission Limitations for Air Oxidation Processes.	11/15/94	09/27/95, 60 FR 49770.	
218.522	Savings Clause	11/15/94	09/27/95, 60 FR 49770.	
218.523	Compliance	11/15/94	09/27/95, 60 FR 49770.	
218.524	Determination of Applicability	11/15/94	09/27/95, 60 FR 49770.	
218.525	Emission Limitations for Air Oxidation Processes.	11/15/94	09/27/95, 60 FR 49770.	
218.526	Testing and Monitoring	08/16/91	09/09/94, 59 FR 46562.	
	Subpart W: Agriculture			
218.541	Pesticide Exception	09/27/93	09/09/94, 59 FR 46562.	
	Subpart X: Construction			
218.561	Architectural Coatings	08/16/91	09/09/94, 59 FR 46562.	
218.562	Paving Operations	09/27/93	09/09/94, 59 FR 46562.	
218.563	Cutback Asphalt	08/16/91	09/09/94, 59 FR 46562.	
	Subpart Y: Gasoline Distribution			
218.581	Bulk Gasoline Plants	09/27/93	09/09/94, 59 FR 46562.	
218.582	Bulk Gasoline Terminals	09/27/93	09/09/94, 59 FR 46562.	
218.583	Gasoline Dispensing Operations—Storage Tank Filling Operations.	12/23/13	03/13/15, 80 FR 13248.	
218.584	Gasoline Delivery Vessels	09/27/93	09/09/94, 59 FR 46562.	
218.586	Gasoline Dispensing Operations—Motor Vehicle Fueling Operations.	12/23/13	03/13/15, 80 FR 13248.	
	Subpart Z: Dry Cleaners			
218.607	Standards for Petroleum Solvent Dry Cleaners.	08/16/91	09/09/94, 59 FR 46562.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
218.608	Operating Practices for Petroleum Solvent Dry Cleaners.	09/27/93	09/09/94, 59 FR 46562.	
218.609	Program for Inspection and Repair of Leaks ..	09/27/93	09/09/94, 59 FR 46562.	
218.610	Testing and Monitoring	09/27/93	09/09/94, 59 FR 46562.	
218.611	Applicability for Petroleum Solvent Dry Cleaners.	01/24/94	10/21/96, 61 FR 54556.	
Subpart AA: Paint and Ink Manufacturing				
218.620	Applicability	01/24/94	10/21/96, 61 FR 54556.	
218.621	Exemption for Waterbase Material and Heatset Offset Ink.	09/27/93	09/09/94, 59 FR 46562.	
218.624	Open Top Mills, Tanks, Vats or Vessels	09/27/93	09/09/94, 59 FR 46562.	
218.625	Grinding Mills	08/16/91	09/09/94, 59 FR 46562.	
218.626	Storage Tanks	08/16/91	09/09/94, 59 FR 46562.	
218.628	Leaks	09/27/93	09/09/94, 59 FR 46562.	
218.630	Clean Up	08/16/91	09/09/94, 59 FR 46562.	
218.636	Compliance Schedule	09/27/93	09/09/94, 59 FR 46562.	
218.637	Recordkeeping and Reporting	09/27/93	09/09/94, 59 FR 46562.	
Subpart BB: Polystyrene Plants				
218.640	Applicability	09/27/93	09/09/94, 59 FR 46562.	
218.642	Emissions Limitation at Polystyrene Plants	09/27/93	09/09/94, 59 FR 46562.	
218.644	Emissions Testing	09/27/93	09/09/94, 59 FR 46562.	
Subpart CC: Polyester Resin Product Manufacturing Process				
218.660	Applicability	01/24/94	10/21/96, 61 FR 54556.	
218.666	Control Requirements	01/24/94	10/21/96, 61 FR 54556.	
218.667	Compliance Schedule	01/24/94	10/21/96, 61 FR 54556.	
218.668	Testing	01/24/94	10/21/96, 61 FR 54556.	
218.670	Recordkeeping and Reporting for Exempt Emission Units.	01/24/94	10/21/96, 61 FR 54556.	
218.672	Recordkeeping and Reporting for Subject Emission Units.	01/24/94	10/21/96, 61 FR 54556.	
Subpart DD: Aerosol Can Fillings				
218.680	Applicability	01/24/94	10/21/96, 61 FR 54556.	
218.686	Control Requirements	05/09/95	03/12/97, 62 FR 11327.	
218.688	Testing	01/24/94	10/21/96, 61 FR 54556.	
218.690	Recordkeeping and Reporting for Exempt Emission Units.	01/24/94	10/21/96, 61 FR 54556.	
218.692	Recordkeeping and Reporting for Subject Emission Units.	01/24/94	10/21/96, 61 FR 54556.	
Subpart GG: Marine Terminals				
218.760	Applicability	10/25/94	04/03/95, 60 FR 16801.	
218.762	Control Requirements	10/25/94	04/03/95, 60 FR 16801.	
218.764	Compliance Certification	10/25/94	04/03/95, 60 FR 16801.	
218.766	Leaks	10/25/94	04/03/95, 60 FR 16801.	
218.768	Testing and Monitoring	10/25/94	04/03/95, 60 FR 16801.	
218.770	Recordkeeping and Reporting	10/25/94	04/03/95, 60 FR 16801.	
Subpart HH: Motor Vehicle Refinishing				
218.780	Emission Limitations	05/09/95	07/25/96, 61 FR 38577.	
218.782	Alternative Control Requirements	05/09/95	07/25/96, 61 FR 38577.	
218.784	Equipment Specifications	01/28/13	10/06/14, 79 FR 60070.	
218.786	Surface Preparation Materials	05/09/95	07/25/96, 61 FR 38577.	
218.787	Work Practices	05/09/95	07/25/96, 61 FR 38577.	
218.788	Testing	05/09/95	07/25/96, 61 FR 38577.	
218.789	Monitoring and Recordkeeping for Control Devices.	05/09/95	07/25/96, 61 FR 38577.	
218.790	General Recordkeeping and Reporting	05/09/95	07/25/96, 61 FR 38577.	
218.791	Compliance Date	05/09/95	07/25/96, 61 FR 38577.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
Subpart II: Fiberglass Boat Manufacturing Materials				
218.890	Applicability	09/14/10	03/23/12, 77 FR 16940.	
218.891	Emission Limitations and Control Requirements.	07/27/11	03/23/12, 77 FR 16940.	
218.892	Testing Requirements	07/27/11	03/23/12, 77 FR 16940.	
218.894	Recordkeeping and Reporting Requirements	07/27/11	03/23/12, 77 FR 16940.	
Subpart JJ: Miscellaneous Industrial Adhesives				
218.900	Applicability	09/14/10	03/23/12, 77 FR 16940.	
218.901	Emission Limitations and Control Requirements.	07/27/11	03/23/12, 77 FR 16940.	
218.902	Testing Requirements	07/27/11	03/23/12, 77 FR 16940.	
218.903	Monitoring Requirements	07/27/11	03/23/12, 77 FR 16940.	
218.904	Recordkeeping and Reporting Requirements	07/27/11	03/23/12, 77 FR 16940.	
Subpart PP: Miscellaneous Fabricated Product Manufacturing Processes				
218.920	Applicability	01/24/94	10/21/96, 61 FR 54556.	
218.926	Control Requirements	01/24/94	10/21/96, 61 FR 54556.	
218.927	Compliance Schedule	09/27/93	10/21/96, 61 FR 54556.	
218.928	Testing	09/27/93	10/21/96, 61 FR 54556.	
218.929	Cementable and Dress or Performance Shoe Leather.	04/08/03	05/24/04, 69 FR 29446.	
Subpart QQ: Miscellaneous Formulation Manufacturing Processes				
218.940	Applicability	07/16/98	06/18/99, 64 FR 32810.	
218.946	Control Requirements	01/24/94	10/21/96, 61 FR 54556.	
218.947	Compliance Schedule	09/27/93	09/09/94, 59 FR 46562.	
218.948	Testing	09/27/93	09/09/94, 59 FR 46562.	
Subpart RR: Miscellaneous Organic Chemical Manufacturing Processes				
218.960	Applicability	01/24/94	10/21/96, 61 FR 54556.	
218.966	Control Requirements	05/09/95	03/12/97, 62 FR 11327.	
218.967	Compliance Schedule	09/27/93	10/21/96, 61 FR 54556.	
218.968	Testing	09/27/93	10/21/96, 61 FR 54556.	
Subpart TT: Other Emission Units				
218.980	Applicability	05/09/95	03/12/97, 62 FR 11327.	
218.986	Control Requirements	01/24/94	10/21/96, 61 FR 54556.	
218.987	Compliance Schedule	09/27/93	10/21/96, 61 FR 54556.	
218.988	Testing	09/27/93	10/21/96, 61 FR 54556.	
Subpart UU: Recordkeeping and Reporting				
218.990	Exempt Emission Units	09/27/93	10/21/96, 61 FR 54556.	
218.991	Subject Emission Units	01/24/94	10/21/96, 61 FR 54556.	
218.Appendix A:	List of Chemicals Defining Synthetic Organic Chemical and Polymer Manufacturing.	09/27/93	09/09/94, 59 FR 46562.	
218.Appendix B:	VOM Measurement Techniques for Capture Efficiency.	09/27/93	09/09/94, 59 FR 46562.	
218.Appendix C:	Reference Test Methods for Air Oxidation Processes.	09/27/93	09/09/94, 59 FR 46562.	
218.Appendix D:	Coefficients for the Total Resource Effectiveness Index (TRE) Equation.	09/27/93	09/09/94, 59 FR 46562.	
218.Appendix E:	List of Affected Marine Terminals	10/25/94	04/03/95, 60 FR 16801.	
218.Appendix G:	TRE Index Measurements for SOCMI Reactors and Distillation Units.	05/09/95	03/23/98, 63 FR 13784.	
218.Appendix H:	Baseline VOM Content Limitations for Subpart F, Section 218.212 Cross-Line Averaging.	05/09/95	02/13/96, 61 FR 5511	
Part 219: Organic Material Emission Standards and Limitations for the Metro East Area				
Subpart A: General Provisions				
219.100	Introduction	09/27/93	09/09/94, 59 FR 46562.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
219.101	Savings Clause	10/25/94	04/03/95, 60 FR 16801.	
219.102	Abbreviations and Conversion Factors	09/27/93	09/09/94, 59 FR 46562.	
219.103	Applicability	08/16/91	09/09/94, 59 FR 46562.	
219.104	Definitions	09/27/93	09/09/94, 59 FR 46562.	
219.105	Test Methods and Procedures	12/23/13	03/13/15, 80 FR 13248.	
219.106	Compliance Dates	09/14/10	03/23/12, 77 FR 16940.	
219.107	Operation of Afterburners	09/27/93	09/09/94, 59 FR 46562.	
219.108	Exemptions, Variations, and Alternative Means of Control or Compliance Determinations.	08/16/91	09/09/94, 59 FR 46562.	
219.109	Vapor Pressure of Volatile Organic Liquids	09/27/93	09/09/94, 59 FR 46562.	
219.110	Vapor Pressure of Organic Material or Solvent.	09/27/93	09/09/94, 59 FR 46562.	
219.111	Vapor Pressure of Volatile Organic Material	09/27/93	09/09/94, 59 FR 46562.	
219.112	Incorporations by Reference	12/23/13	03/13/15, 80 FR 13248.	
Subpart B: Organic Emissions From Storage and Loading Operations				
219.119	Applicability for VOL	11/15/94	08/08/96, 61 FR 41338.	
219.120	Control Requirements for Storage Containers of VOL.	11/15/94	08/08/96, 61 FR 41338.	
219.121	Storage Containers of VPL	09/27/93	09/09/94, 59 FR 46562.	
219.122	Loading Operations	09/27/93	09/09/94, 59 FR 46562.	
219.123	Petroleum Liquid Storage Tanks	09/27/93	09/09/94, 59 FR 46562.	
219.124	External Floating Roofs	09/27/93	09/09/94, 59 FR 46562.	
219.125	Compliance Dates	11/15/94	08/08/96, 61 FR 41338.	
219.127	Testing VOL Operations	11/15/94	08/08/96, 61 FR 41338.	
219.128	Monitoring VOL Operations	01/28/13	10/06/14, 79 FR 60070.	
219.129	Recordkeeping and Reporting for VOL Operations.	11/15/94	08/08/96, 61 FR 41338.	
Subpart C: Organic Emissions From Miscellaneous Equipment				
219.141	Separation Operations	09/27/93	09/09/94, 59 FR 46562.	
219.142	Pumps and Compressors	08/16/91	09/09/94, 59 FR 46562.	
219.143	Vapor Blowdown	09/27/93	09/09/94, 59 FR 46562.	
219.144	Safety Relief Valves	09/27/93	09/09/94, 59 FR 46562.	
Subpart E: Solvent Cleaning				
219.181	Solvent Cleaning Degreasing Operations	06/25/10	03/23/12, 77 FR 16940.	
219.182	Cold Cleaning	06/09/97	11/26/97, 62 FR 62951.	
219.183	Open Top Vapor Degreasing	09/27/93	09/09/94, 59 FR 46562.	
219.184	Conveyorized Degreasing	09/27/93	09/09/94, 59 FR 46562.	
219.186	Test Methods	09/27/93	09/09/94, 59 FR 46562.	
219.187	Other Industrial Solvent Cleaning Operations	07/27/11	03/23/12, 77 FR 16940.	
Subpart F: Coating Operations				
219.204	Emission Limitations	07/27/11	03/23/12, 77 FR 16940.	
219.205	Daily-Weighted Average Limitations	09/14/10	03/23/12, 77 FR 16940.	
219.206	Solids Basis Calculation	09/27/93	09/09/94, 59 FR 46562.	
219.207	Alternative Emission Limitations	07/27/11	03/23/12, 77 FR 16940.	
219.208	Exemptions From Emission Limitations	10/25/11	04/19/13, 78 FR 23495.	
219.209	Exemption From General Rule on Use of Organic Material.	09/27/93	09/09/94, 59 FR 46562.	
219.210	Compliance Schedule	09/14/10	03/23/12, 77 FR 16940.	
219.211	Recordkeeping and Reporting	07/27/11	03/23/12, 77 FR 16940.	
219.212	Cross-Line Averaging To Establish Compliance for Coating Lines.	09/14/10	03/23/12, 77 FR 16940.	
219.213	Recordkeeping and Reporting for Cross-Line Averaging Participating Coating Lines.	05/09/95	02/13/96, 61 FR 5511.	
219.214	Changing Compliance Methods	05/09/95	02/13/96, 61 FR 5511.	
219.215	Wood Furniture Coating Averaging Approach	02/02/98	05/19/98, 63 FR 27489.	
219.216	Wood Furniture Coating Add-On Control Use	02/02/98	05/19/98, 63 FR 27489.	
219.217	Wood Furniture Coating and Flat Wood Paneling Coating Work Practice Standards.	07/27/11	03/23/12, 77 FR 16940.	
219.218	Work Practice Standards for Paper Coatings, Metal Furniture Coatings, and Large Appliance Coatings.	03/23/10	03/23/12, 77 FR 16940.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
219.219	Work Practice Standards for Automobile and Light-Duty Truck Assembly Coatings and Miscellaneous Metal and Plastic Parts Coatings.	09/14/10	03/23/12, 77 FR 16940.	
Subpart G: Use of Organic Material				
219.301	Use of Organic Material	09/27/93	09/09/94, 59 FR 46562.	
219.302	Alternative Standard	09/27/93	09/09/94, 59 FR 46562.	
219.303	Fuel Combustion Emission Units	09/27/93	09/09/94, 59 FR 46562.	
219.304	Operations With Compliance Program	09/27/93	09/09/94, 59 FR 46562.	
Subpart H: Printing and Publishing				
219.401	Flexographic and Rotogravure Printing	07/27/11	03/23/12, 77 FR 16940.	
219.402	Applicability	06/25/10	03/23/12, 77 FR 16940.	
219.403	Compliance Schedule	06/25/10	03/23/12, 77 FR 16940.	
219.404	Recordkeeping and Reporting	07/27/11	03/23/12, 77 FR 16940.	
219.405	Lithographic Printing: Applicability	06/25/10	03/23/12, 77 FR 16940.	
219.407	Emission Limitations and Control Requirements for Lithographic Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
219.409	Testing for Lithographic Printing	07/27/11	03/23/12, 77 FR 16940.	
219.410	Monitoring Requirements for Lithographic Printing.	06/25/10	03/23/12, 77 FR 16940.	
219.411	Recordkeeping and Reporting for Lithographic Printing.	07/27/11	03/23/12, 77 FR 16940.	
219.412	Letterpress Printing Lines: Applicability	06/25/10	03/23/12, 77 FR 16940.	
219.413	Emission Limitations and Control Requirements for Letterpress Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
219.415	Testing for Letterpress Printing Lines	07/27/11	03/23/12, 77 FR 16940.	
219.416	Monitoring Requirements for Letterpress Printing Lines.	06/25/10	03/23/12, 77 FR 16940.	
219.417	Recordkeeping and Reporting for Letterpress Printing Lines.	07/27/11	03/23/12, 77 FR 16940.	
Subpart Q: Synthetic Organic Chemical and Polymer Manufacturing Plant				
219.421	General Requirements	09/27/93	09/09/94, 59 FR 46562.	
219.422	Inspection Program Plan for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.423	Inspection Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.424	Repairing Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.425	Recordkeeping for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.426	Report for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.427	Alternative Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.428	Open-Ended Valves	09/27/93	09/09/94, 59 FR 46562.	
219.429	Standards for Control Devices	09/27/93	09/09/94, 59 FR 46562.	
219.431	Applicability	05/09/95	03/23/98, 63 FR 13784.	
219.432	Control Requirements	05/09/95	03/23/98, 63 FR 13784.	
219.433	Performance and Testing Requirements	05/09/95	03/23/98, 63 FR 13784.	
219.434	Monitoring Requirements	05/09/95	03/23/98, 63 FR 13784.	
219.435	Recordkeeping and Reporting Requirements	05/09/95	03/23/98, 63 FR 13784.	
219.436	Compliance Date	05/09/95	03/23/98, 63 FR 13784.	
Subpart R: Petroleum Refining and Related Industries; Asphalt Materials				
219.441	Petroleum Refinery Waste Gas Disposal	09/27/93	09/09/94, 59 FR 46562.	
219.442	Vacuum Producing Systems	08/16/91	09/09/94, 59 FR 46562.	
219.443	Wastewater (Oil/Water) Separator	09/27/93	09/09/94, 59 FR 46562.	
219.444	Process Unit Turnarounds	08/16/91	09/09/94, 59 FR 46562.	
219.445	Leaks: General Requirements	09/27/93	09/09/94, 59 FR 46562.	
219.446	Monitoring Program Plan for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.447	Monitoring Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.448	Recordkeeping for Leaks	08/16/91	09/09/94, 59 FR 46562.	
219.449	Reporting for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.450	Alternative Program for Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.451	Sealing Device Requirements	08/16/91	09/09/94, 59 FR 46562.	
219.452	Compliance Schedule for Leaks	09/27/93	09/09/94, 59 FR 46562.	
Subpart S: Rubber and Miscellaneous Plastic Products				
219.461	Manufacture of Pneumatic Rubber Tires	09/27/93	09/09/94, 59 FR 46562.	

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219.462	Green Tire Spraying Operations	09/27/93	09/09/94, 59 FR 46562.	
219.463	Alternative Emission Reduction Systems	09/27/93	09/09/94, 59 FR 46562.	
219.464	Emission Testing	09/27/93	09/09/94, 59 FR 46562.	
	Subpart T: Pharmaceutical Manufacturing			
219.480	Applicability	05/09/95	03/12/97, 62 FR 11327.	
219.481	Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers.	09/27/93	09/09/94, 59 FR 46562.	
219.482	Control of Air Dryers, Production Equipment Exhaust Systems and Filters.	09/27/93	09/09/94, 59 FR 46562.	
219.483	Material Storage and Transfer	09/27/93	09/09/94, 59 FR 46562.	
219.484	In-Process Tanks	08/16/91	09/09/94, 59 FR 46562.	
219.485	Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.486	Other Emission Units	09/27/93	09/09/94, 59 FR 46562.	
219.487	Testing	09/27/93	09/09/94, 59 FR 46562.	
219.488	Monitoring for Air Pollution Control Equipment	08/16/91	09/09/94, 59 FR 46562.	
219.489	Recordkeeping for Air Pollution Control Equipment.	09/27/93	09/09/94, 59 FR 46562.	
	Subpart V: Batch Operations and Air Oxidation Processes			
219.500	Applicability for Batch Operations	05/22/95	04/02/96, 61 FR 14484.	
219.501	Control Requirements for Batch Operations	05/22/95	04/02/96, 61 FR 14484.	
219.502	Determination of Uncontrolled Total Annual Mass Emissions and Actual Weighted Average Flow Rate Values for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
219.503	Performance and Testing Requirements for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
219.504	Monitoring Requirements for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
219.505	Reporting and Recordkeeping for Batch Operations.	05/22/95	04/02/96, 61 FR 14484.	
219.506	Compliance Date	05/22/95	04/02/96, 61 FR 14484.	
219.520	Emission Limitations for Air Oxidation Processes.	11/15/94	09/27/95, 60 FR 49770.	
219.522	Savings Clause	11/15/94	09/27/95, 60 FR 49770.	
219.523	Compliance	11/15/94	09/27/95, 60 FR 49770.	
219.524	Determination of Applicability	11/15/94	09/27/95, 60 FR 49770.	
219.526	Testing and Monitoring	08/16/91	09/09/94, 59 FR 46562.	
	Subpart W: Agriculture			
219.541	Pesticide Exception	09/27/93	09/09/94, 59 FR 46562.	
	Subpart X: Construction			
219.561	Architectural Coatings	08/16/91	09/09/94, 59 FR 46562.	
219.562	Paving Operations	09/27/93	09/09/94, 59 FR 46562.	
219.563	Cutback Asphalt	08/16/91	09/09/94, 59 FR 46562.	
	Subpart Y: Gasoline Distribution			
219.581	Bulk Gasoline Plants	09/27/93	09/09/94, 59 FR 46562.	
219.582	Bulk Gasoline Terminals	09/27/93	09/09/94, 59 FR 46562.	
219.583	Gasoline Dispensing Operations—Storage Tank Filling Operations.	12/23/13	03/13/15, 80 FR 13248.	
219.584	Gasoline Delivery Vessels	09/27/93	09/09/94, 59 FR 46562.	
	Subpart Z: Dry Cleaners			
219.607	Standards for Petroleum Solvent Dry Cleaners.	08/16/91	09/09/94, 59 FR 46562.	
219.608	Operating Practices for Petroleum Solvent Dry Cleaners.	09/27/93	09/09/94, 59 FR 46562.	
219.609	Program for Inspection and Repair of Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.610	Testing and Monitoring	09/27/93	09/09/94, 59 FR 46562.	
219.611	Exemption for Petroleum Solvent Dry Cleaners.	09/27/93	09/09/94, 59 FR 46562.	

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Subpart AA: Paint and Ink Manufacturing				
219.620	Applicability	09/27/93	09/09/94, 59 FR 46562.	
219.621	Exemption for Waterbase Material and Heatset-Offset Ink.	09/27/93	09/09/94, 59 FR 46562.	
219.623	Permit Conditions	09/27/93	09/09/94, 59 FR 46562.	
219.624	Open-Top Mills, Tanks, Vats or Vessels	09/27/93	09/09/94, 59 FR 46562.	
219.625	Grinding Mills	08/16/91	09/09/94, 59 FR 46562.	
219.626	Storage Tanks	08/16/91	09/09/94, 59 FR 46562.	
219.628	Leaks	09/27/93	09/09/94, 59 FR 46562.	
219.630	Clean Up	08/16/91	09/09/94, 59 FR 46562.	
219.636	Compliance Schedule	09/27/93	09/09/94, 59 FR 46562.	
219.637	Recordkeeping and Reporting	09/27/93	09/09/94, 59 FR 46562.	
Subpart BB: Polystyrene Plants				
219.640	Applicability	09/27/93	09/09/94, 59 FR 46562.	
219.642	Emissions Limitation at Polystyrene Plants	09/27/93	09/09/94, 59 FR 46562.	
219.644	Emissions Testing	09/27/93	09/09/94, 59 FR 46562.	
Subpart GG: Marine Terminals				
219.760	Applicability	10/25/94	04/03/95, 60 FR 16801.	
219.762	Control Requirements	10/25/94	04/03/95, 60 FR 16801.	
219.764	Compliance Certification	10/25/94	04/03/95, 60 FR 16801.	
219.766	Leaks	10/25/94	04/03/95, 60 FR 16801.	
219.768	Testing and Monitoring	10/25/94	04/03/95, 60 FR 16801.	
219.770	Recordkeeping and Reporting	10/25/94	04/03/95, 60 FR 16801.	
Subpart HH: Motor Vehicle Refinishing				
219.780	Emission Limitations	05/09/95	07/25/96, 61 FR 38577.	
219.782	Alternative Control Requirements	05/09/95	07/25/96, 61 FR 38577.	
219.784	Equipment Specifications	01/28/13	10/06/14, 79 FR 60070.	
219.786	Surface Preparation Materials	05/09/95	07/25/96, 61 FR 38577.	
219.787	Work Practices	05/09/95	07/25/96, 61 FR 38577.	
219.788	Testing	05/09/95	07/25/96, 61 FR 38577.	
219.789	Monitoring and Recordkeeping for Control Devices.	05/09/95	07/25/96, 61 FR 38577.	
219.791	Compliance Date	05/09/95	07/25/96, 61 FR 38577.	
Subpart II: Fiberglass Boat Manufacturing Materials				
219.890	Applicability	09/14/10	03/23/12, 77 FR 16940.	
219.891	Emission Limitations and Control Requirements.	07/27/11	03/23/12, 77 FR 16940.	
219.892	Testing and Monitoring Requirements	07/27/11	03/23/12, 77 FR 16940.	
219.894	Recordkeeping and Reporting Requirements	07/27/11	03/23/12, 77 FR 16940.	
Subpart JJ: Miscellaneous Industrial Adhesives				
219.900	Applicability	09/14/10	03/23/12, 77 FR 16940.	
219.901	Emission Limitations and Control Requirements.	07/27/11	03/23/12, 77 FR 16940.	
219.902	Testing Requirements	07/27/11	03/23/12, 77 FR 16940.	
219.903	Monitoring Requirements	07/27/11	03/23/12, 77 FR 16940.	
219.904	Recordkeeping and Reporting Requirements	07/27/11	03/23/12, 77 FR 16940.	
Subpart PP: Miscellaneous Fabricated Product Manufacturing Processes				
219.920	Applicability	09/27/93	05/07/96, 61 FR 20455.	
219.923	Permit Conditions	09/27/93	05/07/96, 61 FR 20455.	
219.926	Control Requirements	05/09/95	05/07/96, 61 FR 20455.	
219.927	Compliance Schedule	09/27/93	05/07/96, 61 FR 20455.	
219.928	Testing	09/27/93	05/07/96, 61 FR 20455.	
Subpart QQ: Miscellaneous Formulation Manufacturing Processes				
219.940	Applicability	09/27/93	05/07/96, 61 FR 20455.	
219.943	Permit Conditions	09/27/93	05/07/96, 61 FR 20455.	
219.946	Control Requirements	05/09/95	05/07/96, 61 FR 20455.	

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219.947	Compliance Schedule	09/27/93	05/07/96, 61 FR 20455.	
219.948	Testing	09/27/93	05/07/96, 61 FR 20455.	
	Subpart RR: Miscellaneous Organic Chemical Manufacturing Processes			
219.960	Applicability	09/27/93	05/07/96, 61 FR 20455.	
219.963	Permit Conditions	09/27/93	05/07/96, 61 FR 20455.	
219.966	Control Requirements	05/09/95	05/07/96, 61 FR 20455.	
219.967	Compliance Schedule	09/27/93	05/07/96, 61 FR 20455.	
219.968	Testing	09/27/93	05/07/96, 61 FR 20455.	
	Subpart TT: Other Emission Units			
219.980	Applicability	05/09/95	03/12/97, 62 FR 11327.	
219.983	Permit Conditions	09/27/93	05/07/96, 61 FR 20455.	
219.986	Control Requirements	05/09/95	05/07/96, 61 FR 20455.	
219.987	Compliance Schedule	09/27/93	05/07/96, 61 FR 20455.	
219.988	Testing	09/27/93	05/07/96, 61 FR 20455.	
	Subpart UU: Recordkeeping and Reporting			
219.990	Exempt Emission Units	09/27/93	05/07/96, 61 FR 20455.	
219.991	Subject Emission Units	09/27/93	05/07/96, 61 FR 20455.	
219.Appendix A:	List of Chemicals Defining Synthetic Organic Chemical and Polymer Manufacturing.	09/27/93	09/09/94, 59 FR 46562.	
219.Appendix B:	VOM Measurement Techniques for Capture Efficiency (Repealed).	09/27/93	09/09/94, 59 FR 46562.	
219.Appendix C:	Reference Methods and Procedures	09/27/93	09/09/94, 59 FR 46562.	
219.Appendix D:	Coefficients for the Total Resource Effectiveness Index (TRE) Equation.	09/27/93	09/09/94, 59 FR 46562.	
219.Appendix E:	List of Affected Marine Terminals	02/15/96	04/03/95, 60 FR 16801.	
219.Appendix G:	TRE Index Measurements for SOCMI Reactors and Distillation Units.	05/09/95	03/23/98, 63 FR 13784.	
219.Appendix H:	Baseline VOM Content Limitations for Subpart F, Section 219.212 Cross-Line Averaging.	05/09/95	02/13/96, 61 FR 5511.	
	Part 223: Standards and Limitations for Organic Material Emissions for Area Sources			
	Subpart A: General Provisions			
223.100	Severability	06/08/09	05/06/13, 78 FR 26258.	
223.105	Abbreviations and Acronyms	06/08/09	05/06/13, 78 FR 26258.	
223.120	Incorporations by Reference	06/08/09	05/06/13, 78 FR 26258.	
	Subpart B: Consumer and Commercial Products			
223.200	Purpose	06/08/09	05/06/13, 78 FR 26258.	
223.201	Applicability	05/04/12	05/06/13, 78 FR 26258.	
223.203	Definitions for Subpart B	05/04/12	05/06/13, 78 FR 26258.	
223.205	Standards	05/04/12	05/06/13, 78 FR 26258.	
223.206	Diluted Products	06/08/09	05/06/13, 78 FR 26258.	
223.207	Products Registered Under FIFRA	05/04/12	05/06/13, 78 FR 26258.	
223.208	Requirements for Aerosol Adhesives	05/04/12	05/06/13, 78 FR 26258.	
223.209	Requirements for Floor Wax Strippers	06/08/09	05/06/13, 78 FR 26258.	
223.210	Products Containing Ozone-Depleting Compounds.	06/08/09	05/06/13, 78 FR 26258.	
223.211	Requirements for Adhesive Removers, Aerosol Adhesives, Contact Adhesives, Electrical Cleaners, Electronic Cleaners, Footwear or Leather Care Products, General Purpose Degreasers, and Graffiti Removers.	05/04/12	05/06/13, 78 FR 26258.	
223.220	Requirements for Charcoal Lighter Material	06/08/09	05/06/13, 78 FR 26258.	
223.230	Exemptions	06/08/09	05/06/13, 78 FR 26258.	
223.240	Innovative Product Exemption	06/08/09	05/06/13, 78 FR 26258.	
223.245	Alternative Compliance Plans	06/08/09	05/06/13, 78 FR 26258.	
223.250	Product Dating	06/08/09	05/06/13, 78 FR 26258.	
223.255	Additional Product Dating Requirements	06/08/09	05/06/13, 78 FR 26258.	
223.260	Most Restrictive Limit	06/08/09	05/06/13, 78 FR 26258.	

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223.265	Additional Labeling Requirements for Aerosol Adhesives, Adhesive Removers, Electronic Cleaners, Electrical Cleaners, Energized Electrical Cleaners, and Contact Adhesives.	06/08/09	05/06/13, 78 FR 26258.	
223.270	Reporting Requirements	06/08/09	05/06/13, 78 FR 26258.	
223.275	Special Recordkeeping Requirements for Consumer Products That Contain Perchloroethylene or Methylene Chloride.	06/08/09	05/06/13, 78 FR 26258.	
223.280	Calculating Illinois Sales	06/08/09	05/06/13, 78 FR 26258.	
223.285	Test Methods	06/08/09	05/06/13, 78 FR 26258.	
Subpart C: Architectural and Industrial Maintenance Coatings				
223.300	Purpose	06/08/09	05/06/13, 78 FR 26258.	
223.305	Applicability	05/04/12	05/06/13, 78 FR 26258.	
223.307	Definitions for Subpart C	06/08/09	05/06/13, 78 FR 26258.	
223.310	Standards	06/08/09	05/06/13, 78 FR 26258.	
223.320	Container Labeling Requirements	06/08/09	05/06/13, 78 FR 26258.	
223.330	Reporting Requirements	06/08/09	05/06/13, 78 FR 26258.	
223.340	Compliance Provisions and Test Methods	06/08/09	05/06/13, 78 FR 26258.	
223.350	Alternative Test Methods	06/08/09	05/06/13, 78 FR 26258.	
223.360	Methacrylate Traffic Coating Markings	06/08/09	05/06/13, 78 FR 26258.	
223.370	Test Methods	06/08/09	05/06/13, 78 FR 26258.	
Part 225: Control of Emissions From Large Combustion Sources				
Subpart A: General Provisions				
225.120	Abbreviations and Acronyms	08/31/07	10/16/07, 72 FR 58528.	
225.130	Definitions	08/31/07	10/16/07, 72 FR 58528.	
225.140	Incorporations by Reference	08/31/07	10/16/07, 72 FR 58528.	
225.150	Commence Commercial Operation	08/31/07	10/16/07, 72 FR 58528.	
Subpart B: Control of Mercury Emissions From Coal-Fired Electric Generating Units				
225.233	Multi-Pollutant Standard (MPS)	06/26/09	07/06/12, 77 FR 39943	Only (a), (b), (e), and (g).
225.291	Combined Pollutant Standard: Purpose	06/26/09	07/06/12, 77 FR 39943.	
225.292	Applicability of the Combined Pollutant Standard.	06/26/09	07/06/12, 77 FR 39943.	
225.293	Combined Pollutant Standard: Notice of Intent	06/26/09	07/06/12, 77 FR 39943.	
225.295	Combined Pollutant Standard: Emissions Standards for NO_X and SO_2.	06/26/09	07/06/12, 77 FR 39943.	
225.296	Combined Pollutant Standard: Control Technology Requirements for NO_X, SO_2, and PM Emissions.	06/26/09	07/06/12, 77 FR 39943	Except (d).
Subpart C: Clean Air Act Interstate Rule (CAIR) SO_2 Trading Program				
225.300	Purpose	08/31/07	10/16/07, 72 FR 58528.	
225.305	Applicability	08/31/07	10/16/07, 72 FR 58528.	
225.310	Compliance Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.315	Appeal Procedures	08/31/07	10/16/07, 72 FR 58528.	
225.320	Permit Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.325	Trading Program	08/31/07	10/16/07, 72 FR 58528.	
Subpart D: CAIR NO_X Annual Trading Program				
225.400	Purpose	08/31/07	10/16/07, 72 FR 58528.	
225.405	Applicability	08/31/07	10/16/07, 72 FR 58528.	
225.410	Compliance Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.415	Appeal Procedures	08/31/07	10/16/07, 72 FR 58528.	
225.420	Permit Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.425	Annual Trading Budget	08/31/07	10/16/07, 72 FR 58528.	
225.430	Timing for Annual Allocations	08/31/07	10/16/07, 72 FR 58528.	
225.435	Methodology for Calculating Annual Allocations.	08/31/07	10/16/07, 72 FR 58528.	
225.440	Annual Allocations	08/31/07	10/16/07, 72 FR 58528.	
225.445	New Unit Set-Aside (NUSA)	08/31/07	10/16/07, 72 FR 58528.	
225.450	Monitoring, Recordkeeping and Reporting Requirements for Gross Electrical Output and Useful Thermal Energy.	08/31/07	10/16/07, 72 FR 58528.	

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225.455	Clean Air Set-Aside (CASA)	08/31/07	10/16/07, 72 FR 58528.	
225.460	Energy Efficiency and Conservation, Renewable Energy, and Clean Technology Projects.	08/31/07	10/16/07, 72 FR 58528.	
225.465	Clean Air Set-Aside (CASA) Allowances	08/31/07	10/16/07, 72 FR 58528.	
225.470	Clean Air Set-Aside (CASA) Applications	08/31/07	10/16/07, 72 FR 58528.	
225.475	Agency Action on Clean Air Set-Aside (CASA) Applications.	08/31/07	10/16/07, 72 FR 58528.	
225.480	Compliance Supplement Pool	08/31/07	10/16/07, 72 FR 58528.	
Subpart E: CAIR NO_X Ozone Season Trading Program				
225.500	Purpose	08/31/07	10/16/07, 72 FR 58528.	
225.505	Applicability	08/31/07	10/16/07, 72 FR 58528.	
225.510	Compliance Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.515	Appeal Procedures	08/31/07	10/16/07, 72 FR 58528.	
225.520	Permit Requirements	08/31/07	10/16/07, 72 FR 58528.	
225.525	Ozone Season Trading Budget	08/31/07	10/16/07, 72 FR 58528.	
225.530	Timing for Ozone Season Allocations	08/31/07	10/16/07, 72 FR 58528.	
225.535	Methodology for Calculating Ozone Season Allocations.	08/31/07	10/16/07, 72 FR 58528.	
225.540	Ozone Season Allocations	08/31/07	10/16/07, 72 FR 58528.	
225.545	New Unit Set-Aside (NUSA)	08/31/07	10/16/07, 72 FR 58528.	
225.550	Monitoring, Recordkeeping and Reporting Requirements for Gross Electrical Output and Useful Thermal Energy.	08/31/07	10/16/07, 72 FR 58528.	
225.555	Clean Air Set-Aside (CASA)	08/31/07	10/16/07, 72 FR 58528.	
225.560	Energy Efficiency and Conservation, Renewable Energy, and Clean Technology Projects.	08/31/07	10/16/07, 72 FR 58528.	
225.565	Clean Air Set-Aside (CASA) Allowances	08/31/07	10/16/07, 72 FR 58528.	
225.570	Clean Air Set-Aside (CASA) Applications	08/31/07	10/16/07, 72 FR 58528.	
225.575	Agency Action on Clean Air Set-Aside (CASA) Applications.	08/31/07	10/16/07, 72 FR 58528.	
225.Appendix A:	Specified EGUs for Purposes of the CPS (Midwest Generation's Coal-Fired Boilers as of July 1, 2006).	06/26/09	07/06/12, 77 FR 39943.	
Subchapter i: Open Burning				
Part 237: Open Burning				
Subpart A: General Provisions				
237.101	Definitions	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 401.
237.102	Prohibitions	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 402.
237.103	Explosive Wastes	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 405.
237.110	Local Enforcement	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 406.
237.120	Exemptions	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 403.
Subpart B: Permits				
237.201	Permits	09/07/71	05/31/72, 37 FR 10862	Approved as Rule 404.
Subchapter k: Emission Standards and Limitations for Mobile Sources				
Part 240: Mobile Sources				
Subpart A: Definitions and General Provisions				
240.101	Preamble	12/20/94	08/13/14, 79 FR 47377.	
240.102	Definitions	02/01/12	08/13/14, 79 FR 47377.	
240.103	Prohibitions	04/14/72	08/13/14, 79 FR 47377.	
240.104	Inspection	02/01/12	08/13/14, 79 FR 47377.	
240.105	Penalties	02/01/12	08/13/14, 79 FR 47377.	
240.106	Determination of Violation	02/01/12	08/13/14, 79 FR 47377.	
240.107	Incorporations by Reference	03/18/11	08/13/14, 79 FR 47377.	
Subpart B: Emissions				
240.121	Smoke Emissions	02/01/12	08/13/14, 79 FR 47377.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
240.122	Diesel Engine Emissions Standards for Locomotives.	04/07/92	08/13/14, 79 FR 47377.	
240.123	Liquid Petroleum Gas Fuel Systems	02/01/12	08/13/14, 79 FR 47377.	
Subpart C: Smoke Opacity Standards and Test Procedures for Diesel-Powered Heavy Duty Vehicles				
240.140	Applicability	02/26/01	08/13/14, 79 FR 47377.	
240.141	Smoke Opacity Standards and Test Procedures for Diesel-Powered Heavy Duty Vehicles.	02/26/01	08/13/14, 79 FR 47377.	
Subpart D: Steady-State Idle Mode Test Emission Standards				
240.151	Applicability	02/01/12	08/13/14, 79 FR 47377.	
240.152	Steady-State Idle Mode Vehicle Exhaust Emission Standards.	03/18/11	08/13/14, 79 FR 47377.	
240.153	Compliance Determination	03/18/11	08/13/14, 79 FR 47377.	
Subpart F: Evaporative Test Standards				
240.171	Applicability	02/01/12	08/13/14, 79 FR 47377.	
240.172	Evaporative System Integrity Test Standards	07/13/98	08/13/14, 79 FR 47377.	
Subpart G: On-Road Remote Sensing Test Emission Standards				
240.181	Applicability	03/18/11	08/13/14, 79 FR 47377.	
240.182	On-Road Remote Sensing Emission Standards.	03/18/11	08/13/14, 79 FR 47377.	
240.183	Compliance Determination	07/13/98	08/13/14, 79 FR 47377.	
Subpart H: On-Board Diagnostic Test Standards				
240.191	Applicability	03/18/11	08/13/14, 79 FR 47377.	
240.192	On-Board Diagnostic Test Standards	12/18/01	08/13/14, 79 FR 47377.	
240.193	Compliance Determination	12/18/01	08/13/14, 79 FR 47377.	
Subpart I: Visual Inspection Test Standards				
240.201	Applicability	02/01/12	08/13/14, 79 FR 47377.	
240.202	Visual Inspection Test Standards	02/01/12	08/13/14, 79 FR 47377.	
240.203	Compliance Determination	02/01/12	08/13/14, 79 FR 47377.	
240.Appendix A:	Rule Into Section Table	02/01/12	08/13/14, 79 FR 47377.	
240.Appendix B:	Section Into Rule Table	02/01/12	08/13/14, 79 FR 47377.	
Part 241: Clean Fuel Fleet Program				
Subpart A: General Provisions				
241.101	Other Definitions	09/11/95	03/19/96, 61 FR 11139.	
241.102	Definitions	09/11/95	03/19/96, 61 FR 11139.	
241.103	Abbreviations	09/11/95	03/19/96, 61 FR 11139.	
241.104	Incorporations by Reference	09/11/95	03/19/96, 61 FR 11139.	
Subpart B: General Requirements				
241.110	Applicability	09/11/95	03/19/96, 61 FR 11139.	
241.111	Exemptions	09/11/95	03/19/96, 61 FR 11139.	
241.112	Registration of Fleet Owners or Operators	09/11/95	03/19/96, 61 FR 11139.	
241.113	Control Requirements	11/25/97	02/17/99, 64 FR 7788.	
241.114	Conversions	09/11/95	03/19/96, 61 FR 11139.	
241.115	Operating Requirements	09/11/95	03/19/96, 61 FR 11139.	
Subpart C: Credits				
241.130	Clean Fuel Fleet Credit Program	11/25/97	02/17/99, 64 FR 7788.	
241.131	Credit Provisions	09/11/95	03/19/96, 61 FR 11139.	
Subpart D: Recordkeeping and Reporting				
241.140	Reporting Requirements	11/25/97	02/17/99, 64 FR 7788.	
241.141	Recordkeeping Requirements	09/11/95	03/19/96, 61 FR 11139.	
241.142	Report of Credit Activities	09/11/95	03/19/96, 61 FR 11139.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
241.Appendix A:	Emission Standards for Clean Fuel Vehicles	09/11/95	03/19/96, 61 FR 11139.	
241.Appendix B:	Credit Values	11/25/97	02/17/99, 64 FR 7788.	
Subchapter I: Air Quality Standards and Episodes				
Part 243: Air Quality Standards				
Subpart A: General Provisions				
243.101	Definitions	07/29/13	05/20/15, 80 FR 28835.	
243.102	Scope	07/29/13	05/20/15, 80 FR 28835.	
243.103	Applicability	07/29/13	05/20/15, 80 FR 28835.	
243.104	Nondegradation	10/25/11	05/23/13, 78 FR 30770.	
243.105	Air Quality Monitoring Data Influenced by Exceptional Events.	07/29/13	05/20/15, 80 FR 28835.	
243.106	Monitoring	04/14/72	02/21/80, 45 FR 11472.	
243.107	Reference Conditions	11/27/13	06/10/16, 81 FR 37517.	
243.108	Incorporation by Reference	06/09/14	06/10/16, 81 FR 37517.	
Subpart B: Standards and Measurement Methods				
243.120	PM_{10} and $PM_{2.5}$	11/27/13	06/10/16, 81 FR 37517.	
243.122	Sulfur Oxides (Sulfur Dioxide), and	11/27/13	06/10/16, 81 FR 37517.	
243.123	Carbon Monoxide	07/29/13	05/20/15, 80 FR 28835.	
243.124	Nitrogen Oxides (Nitrogen Dioxide as Indicator).	07/29/13	05/20/15, 80 FR 28835.	
243.125	Ozone	07/29/13	05/20/15, 80 FR 28835.	
243.126	Lead, and	07/29/13	05/20/15, 80 FR 28835.	
243.TABLE A	Schedule of Exceptional Event Flagging and Documentation Submission for New or Revised NAAQS.	11/27/13	06/10/16, 81 FR 37517.	
Part 244: Episodes				
Subpart A: Definitions and General Provisions				
244.101	Definitions	05/15/92	01/12/93, 58 FR 3844.	
244.102	Responsibility of the Agency	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
244.103	Determination of Required Actions	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
244.104	Determination of Atmospheric Conditions	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
244.105	Determination of Expected Contaminant Emissions.	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
244.106	Monitoring	05/15/92	01/12/93, 58 FR 3844.	
244.107	Determination of Areas Affected	05/15/92	01/12/93, 58 FR 3844.	
244.108	Failure To Comply With Episode Requirements.	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
244.109	Sealing of Offenders	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 402.
Subpart B: Local Agency Responsibilities				
244.121	Local Agency Responsibilities	05/15/92	01/12/93, 58 FR 3844.	
Subpart C: Episode Action Plans				
244.141	Requirement for Plans	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 404.
244.142	Facilities for Which Action Plans Are Required.	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 404.
244.143	Submission of Plans	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 404.
244.144	Contents of Plans	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 404.
244.145	Processing Procedures	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 404.
Subpart D: Episode Stages				
244.161	Advisory, Alert and Emergency Levels	05/15/92	01/12/93, 58 FR 3844.	
244.162	Criteria for Declaring an Advisory	05/15/92	01/12/93, 58 FR 3844.	
244.163	Criteria for Declaring a Yellow Alert	05/15/92	01/12/93, 58 FR 3844.	
244.164	Criteria for Declaring a Red Alert	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 405(e).
244.165	Criteria for Declaring an Emergency	08/18/72	02/21/80, 45 FR 11472	Approved as Rule 405(e).
244.166	Criteria for Terminating Advisory, Alert and Emergency.	05/15/92	01/12/93, 58 FR 3844.	
244.167	Episode Stage Notification	05/15/92	01/12/93, 58 FR 3844.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
244.168	Contents of Episode Stage Notification	05/15/92	01/12/93, 58 FR 3844.	
244.169	Actions During Episode Stages	05/15/92	01/12/93, 58 FR 3844.	
244.Appendix D:	Required Emission Reduction Actions	05/15/92	01/12/93, 58 FR 3844.	
Chapter II: Environmental Protection Agency				
Part 252: Public Participation in the Air Pollution Permit Program for Major Sources in Nonattainment Areas				
Subpart A: Introduction				
252.101	Purpose	06/01/84	09/25/85, 50 FR 38803.	
252.102	Applicability	06/01/84	09/25/85, 50 FR 38803.	
252.103	Definitions	06/01/84	09/25/85, 50 FR 38803.	
Subpart B: Procedures for Public Review				
252.201	Notice and Opportunity To Comment	06/01/84	09/25/85, 50 FR 38803.	
252.202	Draft Permit and Denial Letter	06/01/84	09/25/85, 50 FR 38803.	
252.203	Availability of Documents	06/01/84	09/25/85, 50 FR 38803.	
252.204	Opportunity for Public Hearing	06/01/84	09/25/85, 50 FR 38803.	
Part 254: Annual Emissions Report				
Subpart A: General Provisions				
254.101	Purpose	07/17/01	05/15/02, 67 FR 34614.	
254.102	Applicability	04/20/12	07/03/13, 67 FR 40013.	
254.103	Definitions	07/17/01	05/15/02, 67 FR 34614.	
254.120	Applicable Pollutants for Annual Emissions Reporting.	07/17/01	05/15/02, 67 FR 34614.	
254.132	Failure To File a Complete Report	07/17/01	05/15/02, 67 FR 34614.	
254.133	Voluntary Submittal of Data	05/14/93	05/15/02, 67 FR 34614.	
254.134	Retention of Records	07/17/01	05/15/02, 67 FR 34614.	
254.135	Reporting of Errors	07/17/01	05/15/02, 67 FR 34614.	
254.136	Confidentiality and Trade Secret Protection	07/17/01	05/15/02, 67 FR 34614.	
254.137	Reporting Schedule	07/17/01	05/15/02, 67 FR 34614.	
254.138	Issuance of Source Inventory Report	07/17/01	05/15/02, 67 FR 34614.	
Subpart B: Reporting Requirements for Large Sources				
254.203	Contents of Subpart B Annual Emissions Report.	07/17/01	05/15/02, 67 FR 34614.	
254.204	Complete Reports	07/17/01	05/15/02, 67 FR 34614.	
Subpart C: Reporting Requirements for Other Sources				
254.303	Contents of Subpart C Annual Emissions Report.	07/17/01	05/15/02, 67 FR 34614.	
254.306	Complete Reports	07/17/01	05/15/02, 67 FR 34614.	
Subpart E: Seasonal Emissions Report Under ERMS				
254.501	Contents of a Seasonal Emissions Report	07/17/01	05/15/02, 67 FR 34614.	
Part 255: General Conformity: Criteria and Procedures				
255.100	Purpose	03/06/97	12/23/97, 62 FR 67000.	
255.110	Federal Requirement	03/06/97	12/23/97, 62 FR 67000.	
255.120	Applicability	03/06/97	12/23/97, 62 FR 67000.	
255.140	Definitions	03/06/97	12/23/97, 62 FR 67000.	
255.150	Abbreviations	03/06/97	12/23/97, 62 FR 67000.	
255.160	Incorporations by Reference	03/06/97	12/23/97, 62 FR 67000.	
255.170	Activities Exempt From Conformity Analysis	03/06/97	12/23/97, 62 FR 67000.	
255.180	Conformity Analysis	03/06/97	12/23/97, 62 FR 67000.	
255.190	Reporting Requirements	03/06/97	12/23/97, 62 FR 67000.	
255.200	Public Participation	03/06/97	12/23/97, 62 FR 67000.	
255.210	Frequency of Conformity Determinations	03/06/97	12/23/97, 62 FR 67000.	
255.220	Criteria for Determining Conformity of General Federal Actions.	03/06/97	12/23/97, 62 FR 67000.	
255.230	Procedures for Conformity Determinations of General Federal Actions.	03/06/97	12/23/97, 62 FR 67000.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
255.240	Mitigation of Air Quality Impacts	03/06/97	12/23/97, 62 FR 67000.	
Part 276: Procedures To Be Followed in the Performance of Inspections of Motor Vehicle Emissions				
Subpart A: General Provisions				
276.101	Purpose and Applicability	06/28/11	08/13/14, 79 FR 47377.	
276.102	Definitions	01/30/12	08/13/14, 79 FR 47377.	
276.103	Abbreviations	06/28/11	08/13/14, 79 FR 47377.	
276.104	Incorporations by Reference	01/30/12	08/13/14, 79 FR 47377.	
276.105	Sunset Provisions	01/30/12	08/13/14, 79 FR 47377.	
Subpart B: Vehicle Emissions Inspection Procedures				
276.201	General Description of Vehicle Emissions Inspection Procedures.	01/30/12	08/13/14, 79 FR 47377.	
276.202	Pollutants To Be Tested—Exhaust Test	09/28/98	08/13/14, 79 FR 47377.	
276.203	Dilution—Steady-State Idle Exhaust Test and Transient Loaded Mode Exhaust Test.	06/28/11	08/13/14, 79 FR 47377.	
276.204	Steady-State Idle Exhaust Emissions Test Procedures.	06/28/11	08/13/14, 79 FR 47377.	
276.205	Evaporative System Integrity Test Procedures	06/28/11	08/13/14, 79 FR 47377.	
276.206	Engine and Fuel Type Modifications	06/14/96	08/13/14, 79 FR 47377.	
276.208	On-Road Remote Sensing Test Procedures	09/28/98	08/13/14, 79 FR 47377.	
276.209	On-Board Diagnostic Test Procedures	06/28/11	08/13/14, 79 FR 47377.	
276.210	Visual Inspection Test Procedures	01/30/12	08/13/14, 79 FR 47377	276.210
Subpart C: Sticker or Certificate Issuance, Display, and Possession				
276.301	General Requirements	06/28/11	08/13/14, 79 FR 47377.	
276.302	Determination of Affected Counties	01/30/12	08/13/14, 79 FR 47377.	
276.303	Emissions Inspection Sticker or Certificate Design and Content.	06/28/11	08/13/14, 79 FR 47377.	
Subpart D: Waiver and Economic Hardship Extension Requirements				
276.401	Waiver Requirements	06/28/11	08/13/14, 79 FR 47377.	
276.403	Denial or Issuance of Waiver	01/30/12	08/13/14, 79 FR 47377.	
276.404	Economic Hardship Extension Requirements	01/30/12	08/13/14, 79 FR 47377.	
276.405	Outside of Affected Counties Annual Exemption Requirements.	01/30/12	08/13/14, 79 FR 47377.	
Subpart E: Test Equipment Specifications				
276.501	General Requirements	06/28/11	08/13/14, 79 FR 47377.	
276.502	Steady-State Idle Exhaust Test Analysis Systems Functional Requirements.	06/28/11	08/13/14, 79 FR 47377.	
276.503	Steady-State Idle Exhaust Test Analysis Systems Performance Criteria.	06/28/11	08/13/14, 79 FR 47377.	
276.504	Evaporative System Integrity Test Functional Requirements and Performance Criteria.	06/28/11	08/13/14, 79 FR 47377.	
276.507	On-Road Remote Sensing Test Systems Functional Requirements and Performance Criteria.	06/28/11	08/13/14, 79 FR 47377.	
276.508	On-Board Diagnostic Test Systems Functional Requirements and Performance Criteria.	06/28/11	08/13/14, 79 FR 47377.	
Subpart F: Equipment Maintenance and Calibration				
276.601	Steady-State Idle Test Equipment Maintenance.	09/28/98	08/13/14, 79 FR 47377.	
276.602	Steady-State Idle Test Equipment Calibration	06/28/11	08/13/14, 79 FR 47377.	
276.603	Evaporative System Integrity Test Maintenance and Calibration.	09/28/98	08/13/14, 79 FR 47377.	
276.604	Record Keeping	06/28/11	08/13/14, 79 FR 47377.	
276.606	On-Road Remote Sensing Test Systems Maintenance and Calibration.	09/28/98	08/13/14, 79 FR 47377.	
276.607	On-Board Diagnostic Test Systems Maintenance and Calibration.	09/28/98	08/13/14, 79 FR 47377.	

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
	Subpart G: Fleet Self-Testing Requirements			
276.701	General Requirements	06/28/11	08/13/14, 79 FR 47377.	
276.702	Fleet Inspection Permit	06/28/11	08/13/14, 79 FR 47377.	
276.703	Fleet Inspection Permittee Operating Requirements.	06/28/11	08/13/14, 79 FR 47377.	
276.704	Private Official Inspection Station Auditing and Surveillance.	06/28/11	08/13/14, 79 FR 47377.	
276.705	Fleet Vehicle Inspection Procedures (Renumbered).	06/14/96	08/13/14, 79 FR 47377.	
	Subpart H: Grievance Procedure			
276.801	General Requirements	06/14/96	08/13/14, 79 FR 47377.	
276.802	Procedure for Filing Grievance	06/28/11	08/13/14, 79 FR 47377.	
276.803	Agency Investigation	06/28/11	08/13/14, 79 FR 47377.	
276.804	Review of Agency's Determination	06/14/96	08/13/14, 79 FR 47377.	
	Subpart I: Notices			
276.901	General Requirements	06/28/11	08/13/14, 79 FR 47377.	
276.902	Vehicle Emissions Test Notice	06/28/11	08/13/14, 79 FR 47377.	
	Subpart J: Reciprocity With Other Jurisdictions			
276.1001	Requirements for Vehicles Registered in Affected Counties and Located in Other Jurisdictions Requiring Vehicle Emissions Inspection.	06/28/11	08/13/14, 79 FR 47377.	
276.1002	Requirements for Vehicles Registered in Other Jurisdictions Requiring Vehicle Emissions Inspection and Located in an Affected County.	06/28/11	08/13/14, 79 FR 47377.	
	Subpart K: Repair Facility Performance Reporting			
276.1101	Requirements for Collecting and Reporting Data Pertaining to the Repair of Vehicles That Failed or Were Rejected From an Emissions Inspection.	06/28/11	08/13/14, 79 FR 47377.	
	Part 283: General Procedures for Emissions Tests Averaging			
	Subpart A: Introduction			
283.110	Purpose	09/11/00	05/09/03, 68 FR 24885.	
283.120	Applicability	09/11/00	05/09/03, 68 FR 24885.	
283.130	Definitions	09/11/00	05/09/03, 68 FR 24885.	
	Subpart B: Procedures for Averaging of Test Results			
283.210	Criteria for Averaging Tests	09/11/00	05/09/03, 68 FR 24885.	
283.220	Test Plan Requirements	09/11/00	05/09/03, 68 FR 24885.	
283.230	Changes to the Test Plan	09/11/00	05/09/03, 68 FR 24885.	
283.240	Averaging Procedure	09/11/00	05/09/03, 68 FR 24885.	
283.250	Compliance Determination	09/11/00	05/09/03, 68 FR 24885.	
	State Statutes			
20 ILCS 605/46.13a.	Civil Administrative Code	09/21/92	08/30/93, 58 FR 45448	Subsection 46.13(a) [Approved Under Public Act 87–1177].
415 ILCS 5/9	Illinois Environmental Protection Act	06/21/96	05/29/02, 67 FR 37323	Section 9(f) [Approved Under Public Act 89–491].
415 ILCS 5/9.1	Illinois Environmental Protection Act	09/17/91	12/17/92, 57 FR 59928	(Ch. 111 1/2, par. 1009.1) par. 1009.1(a), (b), (c), (d) and (f). [Approved Under Public Act 87–555].
415 ILCS 5/9.9	Illinois Environmental Protection Act	07/01/01	11/08/2001, 66 FR 56454	Section 9.9(f) [Approved Under Public Act 92–0012].
415 ILCS 5/39.5	Illinois Environmental Protection Act	09/26/92	08/30/93, 58 FR 45448	Subsection 20 [Approved Under Public Act 87–1213].

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Illinois citation	Title/subject	State effective date	EPA approval date	Comments
625 ILCS 5/13B ..	Illinois Vehicle Code	01/18/94	07/25/96, 61 FR 38582	625 ILCS 5/13B [Approved Under Public Act 88–533].

(d) *EPA approved state source-specific requirements.*

EPA-APPROVED ILLINOIS SOURCE-SPECIFIC REQUIREMENTS

Name of source	Order/permit No.	State effective date	EPA approval date	Comments
Alumax Incorporated, Morris, IL	PCB AS 92–13	09/01/1994	02/01/1996, 61 FR 3575.	
Argonne National Laboratory	PCB AS 03–4	12/18/2003	07/28/2004, 69 FR 44967.	
Bema Film Systems, Incorporated, DuPage Co.	PCB AS 00–11	01/18/2001	11/30/2001, 66 FR 59702.	
Central Can Company (CCC), Chicago, IL.	PCB AS 94–18	08/06/98, eff. 7/01/91.	03/18/1999, 64 FR 13346.	
Chase Products Company, Broadview (Cook Co.).	PCB AS 94–4	05/16/1996	06/09/1997, 62 FR 31341.	
City Water, Light & Power, City of Springfield.	9090046	06/23/2011	07/06/2012, 77 FR 39943.	Joint Construction and Operating Permit.
CP–D Acquisition Company, LLC. (formerly Cromwell-Phoenix, Inc).	PCB AS 03–05	11/20/2003	10/29/2008, 73 FR 64213.	
Ford Motor Company	PCB, AS 02–03	11/21/2002	03/22/2004, 69 FR 13239.	
Ford Motor Company Chicago Assembly Plant.	PCB, AS 05–5	09/01/2005	09/06/2006, 71 FR 52464.	
Greif Packaging, LLC, Naperville, DuPage Co.	PCB AS 2011–01	04/05/2012	10/22/2012, 77 FR 64422.	
IL Power Company's Baldwin Power Station.	PCB 79–7	09/08/1983	04/18/1990, 55 FR 14419.	Emission limits within Paragraph 1 of Final Order.
IPH/Ameren Energy	PCB 14–10	11/21/2013	12/21/2015, 80 FR 79261.	Certificate of Acceptance, filed with the Illinois Pollution Control Board Clerk's Office 12/20/13.
Kincaid Generation, LLC	9050022	06/24/2011	07/06/2012, 77 FR 39943.	Joint Construction and Operating Permit.
Laclede Steel Sulfur dioxide plan	93070030	11/18/93	04/20/1994, 59 FR 18752.	FESOP for boilers and reheat furnaces.
Leisure Properties LLC/D/B/A Crownline Boats, West Frankfort, Illinois.	PCB AS 04–01	07/22/2004	04/20/2012, 77 FR 23622.	Effective date identified in error as 07/22/02 in the document heading. Due to ownership change, the Board transferred the adjusted standard to Leisure Properties LLC D/B/A Crownline Boats by Board order AS04-I, effective 10/07/10.
Louis Berkman Company, d/b/a/ the Swenson Spreader Company's Lindenwood, Ogle Co.	PCB, AS 97–5	05/07/1998	05/27/2004, 69 FR 30224.	
LTV Steel Company, Inc.	98120091	05/14/1999	07/14/1999, 64 FR 37847.	Federally Enforceable State Operating Permit.
Midwest Generation, LLC	PCB 12–121	08/23/2012	07/20/2015, 80 FR 42726.	Certificate of Acceptance, dated 08/24/12, filed with the Illinois Pollution Control Board Clerk's Office 08/27/12.
Midwest Generation, LLC	PCB 13–24	04/04/2013	07/20/2015, 80 FR 42726.	Certificate of Acceptance, dated 05/16/13, filed with the Illinois Pollution Control Board Clerk's Office 05/17/13.
National Steel Corporation, Granite City Division.	95010005	10/21/1997	03/11/1998, 63 FR 11842.	Joint Construction and Operating Permit.
Quantum Chemical Corporation, Morris, Aux Sable Township, Grundy Co.	PCB AS 92–14	10/07/1993	04/03/1995, 60 FR 16803.	adjusted standard.
Reynolds Metals Company's McCook Sheet and Plate Plant in McCook, IL (in Cook Co.).	PCB AS 91–8	09/21/1995	01/21/1997, 62 FR 2916.	

EPA-APPROVED ILLINOIS SOURCE-SPECIFIC REQUIREMENTS—Continued

Name of source	Order/permit No.	State effective date	EPA approval date	Comments
Royal Fiberglass Products, d/b/a Viking Pools.	PCB AS 09–14	09/05/2013	07/14/2014, 79 FR 40673.	
Solar Corporation, Libertyville, IL	PCB AS 94–2	07/20/1995	02/23/1998, 63 FR 8855.	
Sun Chemical Corporation, Northlake, IL.	PCB AS 99–4	05/20/1999	09/13/1999, 64 FR 49400.	
Vonco Products, Incorporated, Lake Co.	PCB AS 00–12	01/18/2001	11/30/2001, 66 FR 59704.	

(e) *EPA approved nonregulatory and quasi-regulatory provisions.*

EPA-APPROVED ILLINOIS NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Air quality surveillance network	State-wide	12/20/79	03/04/1981, 46 FR 15137.	
Coal ban	Chicago Area	10/22/73	03/02/1976, 41 FR 8956.	
Compliance schedules	State-wide	03/13/73, 04/03/73, 05/03/73, 06/15/73, and 08/07/73.	03/02/1976, 41 FR 8956.	
Regional haze plan	Statewide	6/24/11	07/06/2012, 77 FR 39943.	
Small business stationary source technical and environmental compliance assistance program.	State-wide	11/12/92	08/30/1993, 58 FR 45451.	
Total Suspended Particulate Control Strategy analysis.	State-wide	10/01/81	09/30/1982, 47 FR 43054.	
Transportation control plan	Chicago Area	04/17/73	03/02/1976, 41 FR 8956.	
Transportation control plan	Chicago Area	04/30/80	01/27/1981, 46 FR 8472.	
Transportation control plan	Chicago Area	08/20/80 and 03/20/81	11/16/1981, 46 FR 56196.	
Transportation control plan	Peoria Area	10/15/80	11/16/1981, 46 FR 56196.	
Transportation control plan	St. Louis Area	04/01/81	11/16/1981, 46 FR 56196.	
Transportation control plans	Chicago and St. Louis areas.	12/03/82	10/04/1990, 55 FR 40658.	
Attainment and Maintenance Plans				
Carbon monoxide attainment demonstration.	Chicago Area	05/04/83	10/04/1990, 55 FR 40658.	
Lead (1978) attainment and maintenance plan.	Granite City area	09/30/83	07/24/1984, 49 FR 29790.	
Lead (2008)—Clean Data Determination.	Chicago Area	N/A	08/25/2015, 80 FR 51131.	
Ozone (1-hour) attainment demonstration.	Chicago area	12/26/00	11/13/2001, 66 FR 56904.	
Ozone (1-hour) attainment demonstration.	St. Louis area	11/15/99, 02/10/00, 04/13/01, and 04/30/01.	6/26/2001, 66 FR 33996.	EPA is disapproving the request for an exemption from the NO_X NSR and certain NO_X conformity requirements for Madison, Monroe, and St. Clair Counties.
Ozone (1-hour) attainment plan revision.	Chicago severe nonattainment area.	04/11/03	09/15/2003, 68 FR 53887.	
Ozone (1-hour) redesignation and maintenance plan.	Jersey County	11/12/93	03/14/1995, 60 FR 13634.	
Ozone (1-hour) redesignation and maintenance plan.	St. Louis Area	12/30/02	05/12/2003, 68 FR 25542.	
Ozone (1-hour revoked) finding of attainment.	Chicago area	01/30/07	12/30/2008, 73 FR 79652.	

EPA-APPROVED ILLINOIS NONREGULATORY AND QUASI-REGULATORY PROVISIONS—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Ozone (8-hour, 1997) Determination of Attainment.	Chicago area	N/A	07/08/2011, 76 FR 40262.	Correction to codification published on 03/12/10 at 75 FR 12088.
Ozone (8-hour, 1997) Determination of Attainment.	St. Louis area	N/A	06/09/2011, 76 FR 33647.	
Ozone (8-hour, 1997) maintenance plan revision.	Chicago area	03/28/14	10/06/2014, 79 FR 60073.	Revised VOC and NO_X Motor Vehicle Emissions Budgets (MVEB) for the year 2025.
Ozone (8-hour, 1997) redesignation and maintenance plan.	Chicago area	07/23/09, and 09/16/11.	08/13/2012, 77 FR 48062.	
Ozone (8-hour, 1997) redesignation and maintenance plan.	St. Louis area	05/26/10, and 09/16/11.	06/12/2012, 77 FR 34819.	
Ozone (8-hour, 2008) Determination of Attainment.	St. Louis area	N/A	06/27/2016, 81 FR 41444.	determination that the area attained by the 07/20/2016 attainment date.
PM_{10} maintenance plan	Granite City area	03/19/96, and 10/15/96.	03/11/1998, 47 FR 11842.	
PM_{10} maintenance plan	Lake Calumet (Southeast Chicago), Cook County.	08/02/05, as supplemented on 09/08/05.	09/22/2005, 70 FR 55545.	
PM_{10} maintenance plan	LaSalle County	06/02/95, and 01/09/96.	08/08/1996, 61 FR 41342.	
PM_{10} maintenance plan	Lyons Township (McCook), Cook County.	08/02/05	09/22/2005, 70 FR 55541.	
$PM_{2.5}$ (1997)—Clean Data Determination.	St. Louis area	N/A	05/23/2011, 76 FR 29652.	
$PM_{2.5}$ (1997)—Determination of Attainment.	Chicago area	N/A	11/27/2009, 74 FR 62243.	
$PM_{2.5}$ (1997)—Determination of Attainment.	St. Louis area	N/A	06/27/2012, 77 FR 38184.	
$PM_{2.5}$ (1997)—maintenance plan and motor vehicle emissions budgets.	Chicago area	10/15/10, supplemented on 09/16/11, and 05/06/13.	10/02/2013, 78 FR 60704.	
Sulfur dioxide control strategy	Cincinnati, Pekin and Elm Grove Townships in Tazewell County and Logan and Limestone Townships in Peoria County.	03/24/83 and 05/03/83	08/08/1984, 49 FR 31685.	Correction to codification published on 02/09/94 at 59 FR 5955.
Sulfur dioxide maintenance plan	Peoria and Hollis Townships in Peoria County and Groveland Township in Tazewell County.	11/10/94	60 FR 17001, 4/4/1995.	
Emission Inventories				
Emission inventory—1990 (1-hour ozone).	Chicago and St. Louis areas.	11/12/93	03/14/1995, 60 FR 13631.	
Emission inventories—2002 (NO_X, primary $PM_{2.5}$, SO_2, ammonia, and VOC).	Chicago area	10/15/10, supplemented on 05/06/13.	10/02/2013, 78 FR 60704.	
Emissions inventory—2002 (1997 8-hour ozone).	St. Louis area	05/26/10, supplemented on 09/16/11.	06/12/2012, 77 FR 34819.	
Emissions inventory—2002 (1997 8-hour ozone).	Chicago area	06/21/06, supplemented on 09/16/11.	08/13/2012, 77 FR 48062.	
Emission inventory—2011 (2008 8-hour ozone).	Chicago and St. Louis areas.	09/03/14	03/07/2016, 81 FR 11671.	
Moderate Area & Above Ozone Requirements				
15 percent rate-of-progress and 3 percent contingency plans.	Chicago and St. Louis areas.	11/15/93	12/18/1997, 62 FR 66279.	
Negative declaration—Natural gas/gasoline processing plants.	State-wide	11/14/85	11/24/1986, 51 FR 42221.	
Negative declaration—Aerospace manufacturing and rework industry.	Chicago and St. Louis areas.	10/11/96	02/11/1997, 62 FR 6127.	

EPA-APPROVED ILLINOIS NONREGULATORY AND QUASI-REGULATORY PROVISIONS—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Negative declaration—Industrial cleaning solvents category.	St. Louis area	10/02/98	01/06/1999, 64 FR 756.	
Negative declaration—Industrial cleaning solvents category.	Chicago area	12/23/99	02/07/2001, 66 FR 9206.	
Negative declaration—Industrial wastewater category.	Chicago area	12/23/99	04/27/2001, 66 FR 21096.	
Negative declaration—Industrial wastewater category.	St. Louis area	10/02/98	01/06/1999, 64 FR 756.	
Negative declaration—Shipbuilding and ship repair industry.	Chicago and St. Louis areas.	10/11/96	02/11/1997, 62 FR 6126.	
NO_X RACT waiver (1997 8-hour ozone).	Chicago and St. Louis areas.	07/29/10	02/22/2011, 76 FR 9655.	
NO_X waiver—RACT, NSR, vehicle I/M, and general conformity.	Chicago severe nonattainment area.	07/13/94	01/26/1996, 61 FR 2428.	does not cover the exemption of NO_X transportation conformity requirements.
NO_X waiver—transportation conformity requirements.	Chicago severe nonattainment area.	06/20/95	02/12/1996, 61 FR 5291.	
Photochemical assessment ambient monitoring system (PAMS).		11/04/93	02/25/1994, 59 FR 9091.	
Post–1996 Rate Of Progress Plan.	Chicago area	12/18/97, 12/17/99, 01/14/00, 01/21/00, and 02/17/00.	12/18/2000, 65 FR 78961.	Includes Contingency measure plan and Transportation Control Measures (TCMs).
Transportation control measures as part of the 15 percent rate-of-progress and 3 percent contingency plans.	St. Louis area	11/15/93	12/18/1997, 62 FR 66279.	Work trip reductions; transit improvements; and traffic flow improvements.
Vehicle miles traveled (VMT) SIP and, transportation control measures (TCMs) as part of the 15 percent rate-of-progress plan.	Chicago area	07/14/1994	09/21/1995, 60 FR 48896.	
Section 110(a)(2) Infrastructure Requirements				
1997 8-hour Ozone NAAQS Infrastructure Requirements.	Statewide	12/12/07	7/13/2011, 76 FR 41075.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(ii), (E) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(C) and (J) with respect to PSD have been disapproved.
1997 $PM_{2.5}$ NAAQS Infrastructure Requirements.	Statewide	12/12/07	7/13/2011, 76 FR 41075.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(ii), (E) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(C) and (J) with respect to PSD have been disapproved.
2006 24-hour $PM_{2.5}$ NAAQS Infrastructure Requirements.	Statewide	08/09/11, supplemented on 08/25/11, and 06/27/12.	8/26/2015, 80 FR 51730.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (E)(i), (E)(iii), (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(E)(ii), (D)(ii) and the PSD portions of (C), (D)(i)(II), and (J) have been disapproved.

EPA-APPROVED ILLINOIS NONREGULATORY AND QUASI-REGULATORY PROVISIONS—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
2008 Lead NAAQS Infrastructure Requirements.	Statewide	12/31/12	7/16/2014, 79 FR 41439.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(I), (D)(i)(II) with respect to visibility protection, (E)(i), (E)(iii), (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(D)(ii) and the PSD portions of (C), (D)(i)(II), and (J) have been disapproved.
2008 Ozone NAAQS Infrastructure Requirements.	Statewide	12/31/12	8/26/2015, 80 FR 51730.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (E)(i), (E)(iii), (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(D)(ii), (E)(ii), and the PSD portions of (C), (D)(i)(II), and (J) have been disapproved.
2010 NO_2 NAAQS Infrastructure Requirements.	Statewide	12/31/12	5/22/2015, 80 FR 29535.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(I), (D)(i)(II) with respect to visibility protection, (E)(i), (E)(iii), (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(D)(ii) and the PSD portions of (C), (D)(i)(II), and (J) have been disapproved.
2010 SO_2 NAAQS Infrastructure Requirements.	Statewide	12/31/12	5/22/2015, 80 FR 29535.	CAA elements 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (E)(i), (E)(iii), (F) through (H), (J) except for prevention of significant deterioration (PSD), and (K) through (M) have been approved. CAA elements 110(a)(2)(D)(ii) and the PSD portions of (C), (D)(i)(II), and (J) have been disapproved.

§ 52.729 [Removed and reserved]

■ 4. Remove and reserve § 52.729.

§ 52.745 [Removed and reserved]

■ 5. Remove and reserve § 52.745.

§ 52.746 [Removed and reserved]

■ 6. Remove and reserve § 52.746.

[FR Doc. 2017–13659 Filed 6–29–17; 8:45 am]

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Part V

Nuclear Regulatory Commission

10 CFR Parts 170 and 171
Revision of Fee Schedules; Fee Recovery for Fiscal Year 2017; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

[NRC–2016–0081]

RIN 3150–AJ73

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2017

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending the licensing, inspection, special project, and annual fees charged to its applicants and licensees. These amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990 as amended (OBRA–90), which requires the NRC to recover approximately 90 percent of its annual budget through fees.

DATES: This final rule is effective on August 29, 2017.

ADDRESSES: Please refer to Docket ID NRC–2016–0081 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0081. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. For the convenience of the reader, the ADAMS accession numbers and instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section of this document.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michele Kaplan, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5256, email: *Michele.Kaplan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background; Statutory Authority

The NRC's fee regulations are governed primarily by two laws: (1) The Independent Offices Appropriations Act of 1952 (IOAA) (31 U.S.C. 9701), and (2) OBRA–90. The OBRA–90 statute requires the NRC to recover approximately 90 percent of its budget authority through fees; this fee-recovery requirement may exclude amounts appropriated for Waste Incidental to Reprocessing, generic homeland security activities, $5 million for advanced reactor regulatory infrastructure, and Inspector General (IG) services for the Defense Nuclear Facilities Safety Board. The OBRA–90 statute first requires the NRC to use its IOAA authority to collect user fees for NRC work that provides specific benefits to identifiable applicants and licensees (such as licensing work, inspections, special projects). The regulations at part 170 of title 10 of the *Code of Federal Regulations* (10 CFR) authorize these fees. But, because the NRC's fee recovery under the IOAA (10 CFR part 170) does not equal 90 percent of the NRC's budget authority, the NRC also assesses generic ''annual fees'' under 10 CFR part 171 to recover the remaining fees necessary to achieve OBRA–90's 90-percent fee recovery. These annual fees recover generic regulatory costs that are not otherwise collected through 10 CFR part 170.

II. Discussion

FY 2017 Fee Collection—Overview

The NRC is issuing the FY 2017 final fee rule based on the Consolidated Appropriations Act, 2017 (Pub. L. 115–31), in the amount of $917.1 million, a decrease of $85.0 million from FY 2016. As explained previously, certain portions of the NRC's total budget are excluded from the NRC's fee-recovery amount—specifically, these exclusions include: $1.3 million for waste-incidental-to-reprocessing activities, $1.0 million for IG services for the Defense Nuclear Facilities Safety Board, and $15.8 million and for generic homeland security activities. Also, for the first time, the enacted budget includes $5 million for advanced reactor infrastructure, which is required to be excluded from the fee base. Additionally, OBRA–90 requires the NRC to recover only approximately 90 percent of the remaining budget authority, leaving the remaining 10 percent to be funded by a congressional appropriation.

After accounting for the OBRA–90 exclusions, this 10-percent appropriation, and net billing adjustments (the sum of unpaid current year invoices (estimated) minus payments for prior year invoices) the NRC must bill approximately $805.9 million in FY 2017 to licensees. Of this amount, the NRC estimates that $297.3 million will be recovered through 10 CFR part 170 user fees, which leaves approximately $508.6 million to be recovered through 10 CFR part 171 annual fees. Table I summarizes the fee-recovery amounts for the FY 2017 final fee rule using the enacted budget and taking into account excluded activities, the 10-percent appropriation, and net billing adjustments (individual values may not sum to totals due to rounding). The FY 2017 appropriation includes access to $23.0 million in carryover funds. The use of carry over funds allows the NRC to accomplish the work needed without additional costs to licensees because fees are calculated based on the new appropriation and not carryover funds.

TABLE I—BUDGET AND FEE RECOVERY AMOUNTS

[Dollars in millions]

	FY 2016 final rule	FY 2017 final rule	Percentage change
Total Budget Authority	$1,002.1	$917.1	−8.5
Less Excluded Fee Items	−21.1	−23.1	9.5
Balance	$981.0	$894.0	−8.9
Fee Recovery Percent	90	90	0.0
Total Amount to be Recovered:	$882.9	$804.6	−8.9
10 CFR part 171 Billing Adjustments:			
Unpaid Current Year Invoices (estimated)	6.3	6.2	−1.6
Less Prior Year Billing Credit for Transportation Fee Class	−0.2	0.0	100.0
Less Payments Received in Current Year for Previous Year Invoices (estimated)	−5.6	−4.9	−12.5
Subtotal	0.5	1.3	160.0
Amount to be Recovered through 10 CFR parts 170 and 171 Fees	$883.4	$805.9	−8.8
Less Estimated 10 CFR part 170 Fees	−332.7	−297.3	−10.7
10 CFR Part 171 Fee Collections Required	$550.7	$508.6	−7.6

FY 2017 Fee Collection—Hourly Rate

The NRC uses an hourly rate to assess fees for specific services provided by the NRC under 10 CFR part 170. The hourly rate also helps determine flat fees (which are used for the review of certain types of license applications). This rate would be applicable to all activities for which fees are assessed under §§ 170.21 and 170.31.

The NRC's hourly rate is derived by adding the budgeted resources for: (1) Mission-direct program salaries and benefits; [1] (2) mission-indirect program support; [2] and (3) agency support,[3] which includes corporate support and the IG, and then dividing this sum by total mission-direct full-time equivalent (FTE) converted to hours. The mission-direct FTE converted to hours is the product of the mission-direct FTE multiplied by the estimated annual mission-direct FTE productive hours. The following shows the hourly rate calculation:

$$\frac{\text{Budgeted Resources}^{4}\quad 787.4 \text{ million}}{\text{Mission-Direct FTE Converted to Hours}\quad 1{,}996 \times 1{,}500} = \text{Hourly Rate} = \$263$$

For FY 2017, the NRC is decreasing the hourly rate from $265 to $263. The 0.8 percent decrease in the FY 2017 hourly rate is due primarily to the decline in total budgetary resources and an increase in productive hours worked, offset by a decline in mission-direct FTE from FY 2016 to FY 2017. The FY 2017 estimated annual direct hours per staff is 1,500 hours, up from 1,440 hours in FY 2016. The productive-hours assumption reflects the average number of hours that a mission-direct employee spends on mission-direct work in a given year. This excludes hours charged to annual leave, sick leave, holidays, training and general administration tasks. Table II shows the hourly rate calculation methodology. The FY 2016 amounts are provided for comparison.

TABLE II—HOURLY RATE CALCULATION

[Dollars in millions]

	FY 2016 final rule	FY 2017 final rule	Percentage change
Mission-Direct Program Salaries & Benefits	$369.6	$340.6	−7.9
Mission-Indirect Program Support	140.6	137.3	−2.3

[1] Mission-direct program salaries and benefits resources are allocated to perform core work activities committed to fulfilling the agency's mission of protecting the public health and safety, promoting the common defense and security, and protecting the environment. The majority of the resources assigned under the direct business lines (Operating Reactors, New Reactors, Fuel Facilities, Nuclear Materials Users, Decommissioning and Low-Level Waste, and Spent Fuel Storage and Transportation) are core work activities considered mission-direct.

[2] Mission-indirect program support resources are those that support the core mission-direct activities. They include, for example, supervisory and nonsupervisory support and mission travel and training. Supervisory and nonsupervisory support and mission travel and training resources assigned under direct business line structure are considered mission-indirect due to their supporting role of the core mission activities.

[3] Agency support (corporate support and the IG) resources are located in executive, administrative, and other support offices such as the Office of the Commission, the Office of the Secretary, the Office of the Executive Director for Operations, the Offices of Congressional and Public Affairs, the Office of the Inspector General, the Office of Administration, the Office of the Chief Financial Officer, the Office of the Chief Information Officer, the Office of the Chief Human Capital Officer and the Office of Small Business and Civil Rights. These budgeted costs administer the corporate or shared efforts that more broadly support the activities of the agency. These activities also include information technology services, human capital services, financial management, and administrative support.

[4] Does not include contract dollars billed to licensees separately.

TABLE II—HOURLY RATE CALCULATION—Continued

[Dollars in millions]

	FY 2016 final rule	FY 2017 final rule	Percentage change
Agency Support (Corporate Support and the IG)	314.0	309.6	−1.4
Subtotal	824.2	787.5	−4.5
Less Offsetting Receipts [5]	−0.1	−0.1	−31.2
Total Budgeted Resources Included in Hourly Rate	824.1	787.4	−4.5
Mission-Direct FTE (Whole numbers)	2,157	1,996	−7.5
Mission-Direct FTE productive hours	1,440	1,500	4.2
Mission-Direct FTE Converted to Hours (Mission-Direct FTE multiplied by Mission-Direct FTE productive hours worked annually) (In Millions)	3.1	3.0	−3.6
Professional Hourly Rate (Total Budget Included in Hourly Rate Divided by FTE Converted to Hours) (Whole Numbers)	265	263	−0.8

FY 2017 Fee Collection—Flat Application Fee Changes

The NRC is amending the flat application fees that it charges to applicants for import and export licenses, applicants for materials licenses and other regulatory services, and holders of materials in its schedule of fees in §§ 170.21 and 170.31, to reflect the revised hourly rate of $263. The NRC calculates these flat fees by multiplying the average professional staff hours needed to process the licensing actions by the proposed professional hourly rate for FY 2017. The NRC analyzes the actual hours spent performing licensing actions and then estimates the average professional staff hours that are needed to process licensing actions as part of its biennial review of fees, which is required by Section 902 of the Chief Financial Officers Act of 1990 (31 U.S.C. 902(8)). The NRC performed this review in FY 2017 and will perform this review again in FY 2019. For the most part, application fees decreased due to a lower hourly rate along with efficiencies achieved in the licensing and inspection programs. Please see the final fee rule work papers (ADAMS Accession No. ML17164A283) for moredetail.

The NRC rounds these flat fees in such a way that ensures both convenience for its stakeholders and that any rounding effects are minimal. Accordingly, fees under $1,000 are rounded to the nearest $10, fees between $1,000 and $100,000 are rounded to the nearest $100, and fees greater than $100,000 are rounded to the nearest $1,000.

The licensing flat fees are applicable for import and export licensing actions (see fee categories K.1. through K.5. of § 170.21), as well as certain materials licensing actions (see fee categories 1.C. through 1.D., 2.B. through 2.F., 3.A. through 3.S., 4.B. through 5.A., 6.A. through 9.D., 10.B., 15.A. through 15.L., 15.R., and 16 of § 170.31). Applications filed on or after the effective date shown in the **DATES** section of this document will be subject to the revised fees in this final rule.

FY 2017 Fee Collection—Fee-Relief and Low-Level Waste (LLW) Surcharge

As previously noted, OBRA–90 requires the NRC to recover only approximately 90-percent of its budget authority. The remaining 10 percent that is not recovered through fees is applied by the NRC to offset certain budgeted activities—see Table III for a full listing. These activities are referred to as ''fee-relief'' activities. Any difference between the 10-percent non-fee-recoverable amount and the budgeted amount of these fee-relief activities results in a fee adjustment (either an increase or decrease) to all licensees' annual fees, based on their percentage share of the NRC's budget.

In FY 2017, the NRC's budgeted fee-relief activities exceeded the 10-percent threshold—therefore, the NRC assessed a fee-relief adjustment (*i.e.,* surcharge) to increase all licensees' annual fees based on their percentage share of the budget. The surcharge is due primarily to a decrease in the 10-percent fee relief threshold, along with increases in infrastructure for medical isotope production and regulatory support to agreement state activities. Table III summarizes the fee-relief activities for FY 2017. The FY 2016 amounts are provided for comparison.

TABLE III—FEE-RELIEF ACTIVITIES

[Dollars in millions]

Fee-relief activities	FY 2016 budgeted costs	FY 2017 budgeted costs	Percentage change
1. Activities not attributable to an existing NRC licensee or class of licensee:			
a. International activities [6]	$12.6	$13.8	9.7
b. Agreement State oversight	12.6	12.9	2.1
c. Scholarships and Fellowships	18.2	17.9	−1.6
d. Medical Isotope Production Infrastructure	1.0	4.2	320.0
2. Activities not assessed under 10 CFR part 170 licensing and inspection fees or 10 CFR part 171 annual fees based on existing law or Commission policy:			

[5] The fees collected by the NRC for Freedom of Information Act (FOIA) services and indemnity (financial protection required of licensees for public liability claims at 10 CFR part 140) are subtracted from the budgeted resources amount when calculating the 10 CFR part 170 hourly rates, per the guidance in Office of Management and Budget (OMB) Circular A–25, User Charges. The budgeted resources for FOIA activities are allocated under the product for Information Services within the Corporate Support business line. The indemnity activities are allocated under the Licensing Actions and the Research & Test Reactors products within the Operating Reactors business line.

[6] This amount includes international assistance activities, conventions and treaties, and specific cooperation activities.

TABLE III—FEE-RELIEF ACTIVITIES—Continued

[Dollars in millions]

Fee-relief activities	FY 2016 budgeted costs	FY 2017 budgeted costs	Percentage change
a. Fee exemption for nonprofit educational institutions	10.1	9.7	−3.9
b. Costs not recovered from small entities under 10 CFR 71.16(c)	8.5	7.4	−12.9
c. Regulatory support to Agreement States	16.5	18.5	11.8
d. Generic decommissioning/reclamation (not related to the power reactor and spent fuel storage fee classes)	15.2	14.6	−3.9
e. *In Situ* leach rulemaking and unregistered general licensees	1.6	1.4	−12.5
f. Potential Department of Defense remediation program MOU activities	1.7	1.1	−34.0
Total fee-relief activities	98.0	101.5	3.5
Less 10 percent of the NRC's total FY budget (less non-fee items)	−98.1	−89.4	−8.9
Fee-Relief Adjustment to be Allocated to All Licensees' Annual Fees	−0.1	12.1	17,357.7

Table IV shows how the NRC allocates the $12.1 million fee-relief adjustment (surcharge) to each license fee class.

In addition to the fee-relief adjustment, the NRC also assesses a generic LLW surcharge of $3.2 million. Disposal of LLW occurs at commercially operated LLW disposal facilities that are licensed by either the NRC or an Agreement State. There are four existing LLW disposal facilities in the United States that accept various types of low-level waste. All are in Agreement States and, therefore, regulated by the State authority. The NRC allocates this surcharge to its licensees based on data available in the DOE Manifest Information Management System. This database contains information on total LLW volumes and NRC usage information from four generator classes: Academic, industry, medical, and utility. The ratio of utility waste volumes to total LLW volumes over a period of time is used to estimate the portion of this surcharge that should be allocated to the power reactors, fuel facilities, and materials fee classes. The materials portion is adjusted to account for the fact that a large percentage of materials licensees are licensed by the Agreement States rather than the NRC.

Table IV shows the surcharge, and its allocation across the various fee classes.

TABLE IV—ALLOCATION OF FEE-RELIEF ADJUSTMENT AND LLW SURCHARGE, FY 2017

[Dollars in millions]

	LLW surcharge		Fee-relief adjustment		Total
	Percent	$	Percent	$	$
Operating Power Reactors	24.0	0.8	85.4	10.3	11.1
Spent Fuel Storage/Reactor Decommissioning	0.0	0.0	3.9	0.5	0.5
Research and Test Reactors	0.0	0.0	0.2	0.0	0.0
Fuel Facilities	62.0	2.0	4.5	0.6	2.5
Materials Users	14.0	0.4	3.6	0.4	0.8
Transportation	0.0	0.0	0.6	0.1	0.1
Rare Earth Facilities	0.0	0.0	0.0	0.0	0.0
Uranium Recovery	0.0	0.0	1.8	0.2	0.2
Total	100.0	3.2	100.0	12.1	15.2

FY 2017 Fee Collection—Revised Annual Fees

In accordance with SECY–05–0164, ''Annual Fee Calculation Method,'' dated September 15, 2005 (ADAMS Accession No. ML052580332), the NRC re-baselines its annual fees every year. Re-baselining entails analyzing the budget in detail and then allocating the budgeted costs to various classes or subclasses of licensees. It also includes updating the number of NRC licensees in its fee calculation methodology.

The NRC revised its annual fees in §§ 171.15 and 171.16 to recover approximately 90 percent of the NRC's FY 2017 budget authority (less non-fee amounts and the estimated amount to be recovered through 10 CFR part 170 fees). The total estimated 10 CFR part 170 collections for this final rule are $297.3 million, a decrease of $35.4 million from the FY 2016 final rule. The NRC, therefore, must recover $508.6 million through annual fees from its licensees, which is a decrease of $42.1 million from the FY 2016 final rule.

Table V shows the re-baselined fees for FY 2017 for a representative list of categories of licensees. The FY 2016 amounts are provided for comparison.

TABLE V—RE-BASELINED ANNUAL FEES

Class/category of licenses	FY 2016 final annual fee	FY 2017 final annual fee	Percentage change
Operating Power Reactors	$4,659,000	$4,308,000	−7.5

TABLE V—RE-BASELINED ANNUAL FEES—Continued

Class/category of licenses	FY 2016 final annual fee	FY 2017 final annual fee	Percentage change
+ Spent Fuel Storage/Reactor Decommissioning	197,000	188,000	−4.6
Total, Combined Fee	4,856,000	4,496,000	−7.4
Spent Fuel Storage/Reactor Decommissioning	197,000	188,000	−4.6
Research and Test Reactors/Non-power Reactors	81,500	81,400	−0.1
High Enriched Uranium Fuel Facility	7,867,000	7,700,000	−2.1
Low Enriched Uranium Fuel Facility	2,736,000	2,790,000	2.0
UF_6 Conversion and Deconversion Facility	1,625,000	1,590,000	−2.2
Conventional Mills	38,900	38,900	0.0
Typical Materials Users:			
Radiographers (Category 3O)	26,000	27,000	3.8
Well Loggers (Category 5A)	14,500	16,000	10.3
All Other Specific Byproduct Material Licenses (Category 3P)	7,900	9,300	17.7
Broad Scope Medical (Category 7B)	37,400	33,800	−9.6

The work papers that support this final rule show in detail how the NRC allocated the budgeted resources for each class of licenses and how the fees are calculated.

Paragraphs a. through h. of this section describe budgetary resources allocated to each class of licensees and the calculations of the re-baselined fees. For more information about detailed fee calculations for each class, please consult the accompanying work papers.

a. Fuel Facilities

The NRC will collect $33.9 million in annual fees from the fuel facility class.

TABLE VI—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources	$40.5	$33.9	−16.3
Less estimated 10 CFR part 170 receipts	−11.7	−9.6	−17.9
Net 10 CFR part 171 resources	28.8	24.3	−15.6
Allocated generic transportation	1.1	1.6	45.5
Fee-relief adjustment/LLW surcharge	1.7	2.5	47.1
Billing adjustments	0.0	0.0	0.0
Total remaining required annual fee recovery	31.6	28.4	−10.1

In FY 2017, the fuel facilities budgetary resources decreased due to continued construction delays at multiple sites (including the Shaw Mixed Oxide Fuel Fabrication and the International Isotope facilities) and efficiencies achieved within the licensing and inspection programs, offset by declining estimated 10 CFR part 170 billings for license renewals and amendments, and a reduction of one licensee in the fee class—Centrus Energy Corporation Lead Cascade Gas Centrifuge Enrichment Demonstration facility. Due to the proration rules in our regulation, this licensee will remain for the FY 2017 final fee rule calculation, and be removed from the fee rule for FY 2018.

The NRC allocates annual fees to individual fuel facility licensees based on the effort/fee determination matrix developed in the FY 1999 final fee rule (64 FR 31447; June 10, 1999). To briefly recap, that matrix groups licensees into various categories. The NRC's fuel facility project managers determine the effort levels associated with regulating each category. This is done by assigning separate effort factors for the safety and safeguards activities associated with each category (for more information about this matrix, see the work papers). These effort levels are reflected in Table VII.

TABLE VII—EFFORT FACTORS FOR FUEL FACILITIES, FY 2017

Facility type (fee category)	Number of facilities	Effort factors (percent of total)	
		Safety	Safeguards
High-Enriched Uranium Fuel (1.A.(1)(a))	2	88 (44.0)	96 (55.2)
Low-Enriched Uranium Fuel (1.A.(1)(b))	3	70 (35.0)	30 (17.2)
Limited Operations (1.A.(2)(a))	0	0 (0.0)	0 (0.0)
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	1	3 (1.5)	15 (8.6)
Hot Cell (1.A.(2)(c))	1	6 (3.0)	3 (1.7)
Uranium Enrichment (1.E.)	1	21 (10.5)	23 (13.2)

TABLE VII—EFFORT FACTORS FOR FUEL FACILITIES, FY 2017—Continued

Facility type (fee category)	Number of facilities	Effort factors (percent of total)	
		Safety	Safeguards
UF_6 Conversion and Deconversion (2.A.(1))	1	12 (6.0)	7 (4.0)

For FY 2017, the total budgeted resources for safety activities are $13.8 million. To calculate the annual fee, the NRC allocates this amount to each fee category based on its percent of the total regulatory effort for safety activities. Similarly, the NRC allocates the budgeted resources for safeguards activities, $12.1 million, to each fee category based on its percent of the total regulatory effort for safeguards activities. Finally, the fuel facility fee class' portion of the fee-relief adjustment/LLW surcharge—$2.5 million—is allocated to each fee category based on its percent of the total regulatory effort for both safety and safeguards activities. The annual fee per licensee is then calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category. The fee for each facility is summarized in Table VIII.

TABLE VIII—ANNUAL FEES FOR FUEL FACILITIES

Facility type (fee category)	FY 2016 final annual fee	FY 2017 final annual fee	Percentage change
High-Enriched Uranium Fuel (1.A.(1)(a))	$7,867,000	$7,700,000	−2.1
Low-Enriched Uranium Fuel (1.A.(1)(b))	2,736,000	2,790,000	2.0
Limited Operations (1.A(2)(a))	0.0	0.0	0.0
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	1,539,000	1,507,000	−2.1
Hot Cell (and others) (1.A.(2)(c))	770,000	753,000	−2.2
Uranium Enrichment (1.E.)	3,762,000	3,340,000	−11.2
UF_6 Conversion and Deconversion (2.A.(1))	1,625,000	1,590,000	−2.2

b. Uranium Recovery Facilities

TABLE IX—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources	$12.3	$14.3	16.3
Less estimated 10 CFR part 170 receipts	−11.4	−13.5	18.4
Net 10 CFR part 171 resources	0.9	0.8	−11.1
Allocated generic transportation	N/A	N/A	N/A
Fee-relief adjustment	0.0	0.2	100.0
Billing adjustments	0.0	0.0	0.0
Total required annual fee recovery	0.9	1.0	7.7

In comparison to FY 2016, the FY 2017 budgetary resources for uranium recovery licensees increased due to increased work expected for additional safety and environmental reviews associated with new licensing actions and increased hearing activities. In addition, the NRC regulates DOE's Title I and Title II activities under the Uranium Mill Tailings Radiation Control Act (UMTRCA).[7] For the UMTRCA program, budgetary resources increased for the expected review of five groundwater correction plans and two long term surveillance plans.

Estimated 10 CFR part 170 fees increased due to the Ludeman expansion, Kennecott safety evaluation report, and the Marsland environmental assessment. For the UMTRCA program, 10 CFR part 170 fees decreased due to delays in the submission of the Monument Valley groundwater correction action plan, the Lakeview long-term surveillance plan, and the completion of the review of the Durango site evaporation pond decommissioning plan.

The NRC will collect approximately $1.0 million in annual fees from the uranium recovery facilities fee class for both DOE and non-DOE licensees, an increase of about eight percent from FY 2016. In comparison with FY 2016, non-DOE licensees annual fees will remain flat for most licensees and decrease for some. The NRC computes the 10 CFR part 171 annual fee for the uranium recovery fee class by dividing the total annual fee recovery amount between DOE and the other licensees in this fee class. The final annual fee assessed to DOE includes the costs specifically budgeted for the NRC's UMTRCA Title

[7] The Congress established the two programs, Title I and Title II, under UMTRCA to protect the public and the environment from uranium milling. The UMTRCA Title I program is for remedial action at abandoned mill tailings sites where tailings resulted largely from production of uranium for the weapons program. The NRC also regulates DOE's UMTRCA Title II program, which is directed toward uranium mill sites licensed by the NRC or Agreement States in or after 1978.

I and II activities, as well as 10 percent of the remaining budgeted cost for this fee class. The DOE's UMTRCA annual fee increased because of an increase in budgetary resources combined with a decrease in 10 CFR part 170 billings. The NRC assesses the remaining 90 percent of its budgeted costs to the rest of the licensees in this fee class, as described in the work papers. This is reflected in Table X.

TABLE X—COSTS RECOVERED THROUGH ANNUAL FEES; URANIUM RECOVERY FEE CLASS

Summary of costs	FY 2016 final annual fee	FY 2017 final annual fee	Percentage change
DOE Annual Fee Amount (UMTRCA Title I and Title II) General Licenses:			
UMTRCA Title I and Title II budgeted costs less 10 CFR part 170 receipts	$503,708	$574,595	14.1
10 percent of generic/other uranium recovery budgeted costs	41,157	19,079	−53.6
10 percent of uranium recovery fee-relief adjustment	−94	21,940	23,440.4
Total Annual Fee Amount for DOE (rounded)	545,000	616,000	13.0
Annual Fee Amount for Other Uranium Recovery Licenses:			
90 percent of generic/other uranium recovery budgeted costs less the amounts specifically budgeted for Title I and Title II activities	370,415	171,714	−53.6
90 percent of uranium recovery fee-relief adjustment	−844	197,464	23,496.2
Total Annual Fee Amount for Other Uranium Recovery Licenses	369,571	369,178	0.0

Further, for the non-DOE licensees, the NRC uses a matrix to determine the effort levels associated with conducting the generic regulatory actions for the different (non-DOE) licensees in this fee class; this is similar to the NRC's approach for fuel facilities, described previously.

The matrix methodology for uranium recovery licensees first identifies the licensee categories included within this fee class (excluding DOE). These categories are: Conventional uranium mills and heap leach facilities; uranium *In Situ* Recovery (ISR) and resin ISR facilities; mill tailings disposal facilities; and uranium water treatment facilities. The matrix identifies the types of operating activities that support and benefit these licensees, along with each activity's relative weight (for more information, see the work papers). Table XI displays the benefit factors per licensee and per fee category, for each of the non-DOE fee categories included in the uranium recovery fee class.

TABLE XI—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Conventional and Heap Leach mills (2.A.(2)(a))	1	150	150	10.5
Basic *In Situ* Recovery facilities (2.A.(2)(b))	5	190	950	66.7
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	1	215	215	15.1
11e.(2) disposal incidental to existing tailings sites (2.A.(4))	1	85	85	6.0
Uranium water treatment (2.A.(5))	1	25	25	1.7
Total	9	665	1,425	100

Applying these factors to the approximate $369,178 in budgeted costs to be recovered from non-DOE uranium recovery licensees results in the total annual fees for each fee category. The annual fee per licensee is calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category, as summarized in Table XII.

TABLE XII—ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

[Other than DOE]

Facility type (fee category)	FY 2016 final annual fee	FY 2017 final annual fee	Percentage change
Conventional and Heap Leach mills (2.A.(2)(a))	$38,900	$38,900	0.0
Basic *In Situ* Recovery facilities (2.A.(2)(b))	49,300	49,200	−0.2
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	55,800	55,700	−0.2
11e.(2) disposal incidental to existing tailings sites (2.A.(4))	22,000	22,000	0.0
Uranium water treatment (2.A.(5))	6,500	6,500	0.0

c. Operating Power Reactors

The NRC will collect $426.5 million in annual fees from the power reactor fee class in FY 2017, as shown in Table XIII. The FY 2016 values and percentage change are shown for comparison.

TABLE XIII—ANNUAL FEE SUMMARY CALCULATIONS FOR POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources	$750.4	$670.3	−10.7
Less estimated 10 CFR part 170 receipts	−287.8	−256.3	−10.9
Net 10 CFR part 171 resources	462.6	414.0	−10.5
Allocated generic transportation	1.8	0.3	−83.3
Fee-relief adjustment/LLW surcharge	1.0	11.1	1,110.0
Billing adjustment	0.6	1.1	83.3
Total required annual fee recovery	465.9	426.5	−8.5

In comparison to FY 2016, the operating power reactors budgetary resources decreased in FY 2017 primarily due to fewer resources needed to reduce the licensing actions backlog and a reduction for generic work such as the Fukushima-related rulemaking, ''Station Blackout Mitigation Strategies.'' In addition, budgetary resources for new reactors decreased because of the completed combined operating licenses for Duke Lee, South Texas Project, and Levy and an application withdrawal from Bell Bend.

Compared with FY 2016, 10 CFR part 170 fees decreased due to completion of actions to address the licensing actions backlog, and the transition of Fort Calhoun to decommissioning status in November 2016.

The budgeted costs are divided equally among the 99 currently operating power reactors, resulting in a final 10 CFR part 171 annual fee of $4,308,000 per reactor. Additionally, each licensed power reactor is assessed the FY 2017 spent fuel storage/reactor decommissioning 10 CFR part 171 annual fee of $188,000 (see the discussion that follows). The combined FY 2017 annual fee for power reactors is, therefore, $4,496,000 which is a decrease from the combined FY 2016 10 CFR part 171 annual fee of $4,856,000.

On May 24, 2016 (81 FR 32617), the NRC published a final rule that amended its licensing, inspection, and annual fee regulations to establish a variable annual fee structure for light-water small modular reactors (SMRs). Under the variable annual fee structure, effective June 23, 2016, an SMR's annual fee would be calculated as a function of its licensed thermal power rating. Currently, there are no operating SMRs; therefore, the NRC will not assess an annual fee in FY 2017 for this type of licensee.

d. Spent Fuel Storage/Reactors in Decommissioning

To collect the budgeted resources for spent fuel storage/reactor decommissioning, the NRC will collect $23.0 million in annual fees from 10 CFR part 50 power reactors and from 10 CFR part 72 licensees who do not hold a 10 CFR part 50 license.

TABLE XIV—ANNUAL FEE SUMMARY CALCULATIONS FOR THE SPENT FUEL STORAGE/REACTOR IN DECOMMISSIONING FEE CLASS

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources	$30.5	$29.5	−3.3
Less estimated 10 CFR part 170 receipts	−7.5	−7.9	5.3
Net 10 CFR part 171 resources	23.0	21.6	−6.1
Allocated generic transportation costs	1.0	0.8	−20.0
Fee-relief adjustment	0.0	0.5	100.0
Billing adjustments	0.0	0.1	100.0
Total required annual fee recovery	24.0	23.0	−4.2

In comparison to FY 2016, the decrease in annual fee is mainly the result of a decrease in budgetary resources for storage licensing and rulemaking activities and an increase in 10 CFR part 170 estimated billings due to the application for a consolidated interim storage facility for Holtec/Eddy Lea Energy and the technical review of an application submitted by Waste Control Specialists.

The required annual fee recovery amount is divided equally among 122 licensees, resulting in an FY 2017 annual fee of $188,000 per licensee.

e. Research and Test Reactors/Non-Power Reactors

The NRC will collect $0.326 million in annual fees from the research and test reactor licensee class.

TABLE XV—ANNUAL FEE SUMMARY CALCULATIONS FOR RESEARCH AND TEST REACTORS/NON-POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources	$3.799	$1.982	−47.8
Less estimated 10 CFR part 170 receipts	−3.510	−1.724	−50.9
Net 10 CFR part 171 resources	0.289	0.258	−10.7
Allocated generic transportation	0.034	0.034	0.0
Fee-relief adjustment	0.000	0.031	100.0
Billing adjustments	0.003	0.003	0.0
Total required annual fee recovery	0.326	0.326	−0.2

In FY 2017, the research and test/non-power reactors budgetary resources decreased due to a decrease in the NRC's workload for licensing medical isotope utilization and production facilities. Accordingly, the estimated 10 CFR part 170 billings decreased for the medical isotope production review. For research and test reactors, in comparison to FY 2016, the 10 CFR part 171 annual fee remained flat. The required annual fee-recovery amount is divided equally among the four research and test reactors subject to annual fees and results in an FY 2017 annual fee of $81,400 for each licensee.

f. Rare Earth

The application for a rare-earth facility has been placed on hold until late FY 2017. Therefore, the NRC has not allocated any budgetary resources to this fee class and will not assess an annual fee in FY 2017 for this fee class.

g. Materials Users

The NRC will collect $35.4 million in annual fees from materials users licensed under 10 CFR parts 30, 40, and 70.

TABLE XVI—ANNUAL FEE SUMMARY CALCULATIONS FOR MATERIALS USERS

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total budgeted resources for licensees not regulated by Agreement States	$33.2	$33.7	1.5
Less estimated 10 CFR part 170 receipts	−1.1	−0.9	−18.2
Net 10 CFR part 171 resources	32.1	32.8	2.2
Allocated generic transportation	2.4	1.6	−33.3
Fee-relief adjustment/LLW surcharge	0.5	0.9	80
Billing adjustments	0.0	0.1	100.0
Total required annual fee recovery	35.0	35.4	1.1

To equitably and fairly allocate the $35.4 million in FY 2017 budgeted costs among approximately 2,700 diverse materials users licensees, the NRC calculates the annual fees for each fee category within this class based on the 10 CFR part 170 application fees and estimated inspection costs for each fee category. Because the application fees and inspection costs are indicative of the complexity of the license, this approach provides a proxy for allocating the generic and other regulatory costs to the diverse categories of licenses based on the NRC's cost to regulate each category. This fee-calculation method also considers the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory cost associated with each category of license.

The annual fee for these categories of materials users' licenses is developed as follows:

Annual fee = Constant × [Application Fee + (Average Inspection Cost/Inspection Priority)] + Inspection Multiplier × (Average Inspection Cost/Inspection Priority) + Unique Category Costs.

For FY 2017, the constant multiplier necessary to recover approximately $25.9 million in general costs (including allocated generic transportation costs) is 1.46 (see work papers for more detail). The average inspection cost is the average inspection hours for each fee category multiplied by the hourly rate of $263. The inspection priority is the interval between routine inspections, expressed in years. The inspection multiplier is the multiple necessary to recover approximately $8.4 million in inspection costs, and is 1.65 for FY 2017. The unique category costs are any special costs that the NRC has budgeted for a specific category of licenses. For FY 2017, approximately $275,000 in budgeted costs for the implementation of revised 10 CFR part 35, ''Medical Use of Byproduct Material'' (unique costs), has been allocated to holders of NRC human-use licenses.

The annual fee assessed to each licensee also includes a share of the fee-relief surcharge assessment of approximately $430,421 allocated to the materials users fee class (see Table IV, ''Allocation of Fee-Relief Adjustment and LLW Surcharge, FY 2017,'' in Section III, ''Discussion,'' of this document), and for certain categories of these licensees, a share of the approximately $442,000 LLW surcharge costs allocated to the fee class. The annual fee for each fee category is shown in § 171.16(d).

h. Transportation

The NRC will collect $5.8 million in annual fees to recover generic transportation budgeted resources. The FY 2016 values are shown for comparison.

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION

[Dollars in millions]

Summary fee calculations	FY 2016 final	FY 2017 final	Percentage change
Total Budgeted Resources	$11.3	$8.9	−21.2
Less Estimated 10 CFR part 170 Receipts	−3.5	−3.1	−11.4
Net 10 CFR part 171 Resources	7.8	5.8	−25.6
Fee-relief adjustment/LLW surcharge	0.0	0.0	0.0
Billing adjustments	0.0	0.0	0.0
Total required annual fee recovery	7.8	5.8	−25.6

In comparison to FY 2016, the total budgetary resources for generic transportation activities decreased due to a reduction in rulemaking activities involving revisions to transportation safety requirements and compatibility with International Atomic Energy Agency Transportation Standards, hence reducing all fee class generic transportation annual fees. The 10 CFR part 170 estimated billings are expected to decrease due in part to a reduction in activities for Areva Federal Services and NAC International.

Consistent with the policy established in the NRC's FY 2006 final fee rule (71 FR 30721; May 30, 2006), the NRC recovers generic transportation costs unrelated to DOE as part of existing annual fees for license fee classes. The NRC assesses a separate annual fee under § 171.16, fee category 18.A. for DOE transportation activities. The amount of the allocated generic resources is calculated by multiplying the percentage of total Certificates of Compliance (CoCs) used by each fee class (and DOE) by the total generic transportation resources to be recovered. The DOE annual fee increase is mainly due to the elimination of a prior year credit totaling approximately $220,000 from FY 2016, as well as a rise in CoCs by 4, or 22 percent.

This resource distribution to the licensee fee classes and DOE is shown in Table XVIII. Specifically, for the research and test reactors fee class, the NRC allocates the distribution to only the licensees that are subject to annual fees. Four CoCs benefit the entire research and test reactor class, but only 4 out of 31 research and test reactors are subject to annual fees. The number of CoCs used to determine the proportion of generic transportation resources allocated to research and test reactors annual fees is adjusted to 0.6 so that the licensees subject to annual fees are charged a fair and equitable portion of the total. For more information see the work papers.

TABLE XVIII—DISTRIBUTION OF GENERIC TRANSPORTATION RESOURCES, FY 2017

[Dollars in millions]

License fee class/DOE	Number of CoCs benefiting fee class or DOE	Percentage of total CoCs	Allocated generic transportation resources
DOE	22.0	24.6	1.4
Operating Power Reactors	5.0	5.6	0.3
Spent Fuel Storage/Reactor Decommissioning	13.0	14.5	0.9
Research and Test Reactors	0.5	0.6	0.0
Fuel Facilities	24.0	26.8	1.6
Materials Users	25.0	27.9	1.6
Total	89.5	100.0	5.8

The NRC assesses an annual fee to DOE based on the 10 CFR part 71 CoCs it holds. The NRC, therefore, does not allocate these DOE-related resources to other licensees' annual fees because these resources specifically support DOE.

FY 2017—Administrative Changes

The NRC makes three administrative changes:

1. Increase Mission-Direct Hours per Full-Time Equivalent in the Hourly Rate Calculation

The hourly rate in 10 CFR part 170 is calculated by dividing the cost per direct FTE by the number of mission-direct hours per direct FTE in a year. ''Mission-direct hours'' are hours charged to mission-direct activities in the Nuclear Reactor Safety Program and Nuclear Materials and Waste Safety Program. The FY 2016 final fee rule used 1,440 hours per direct FTE in the hourly rate calculations. During the FY 2017 budget formulation process, the NRC staff reviewed and analyzed time and labor data from FY 2016 to determine whether it should revise the direct hours per FTE. In FY 2016, the total mission-direct hours charged by direct employees increased due to increased accuracy in coding time to direct work in the time and labor system, as well as decreased time coded for training. The increase in mission-direct hours was apparent in all mission business lines. To reflect this increase in productivity as demonstrated by the time and labor data, the NRC staff determined that the number of mission-direct hours per FTE should increase to 1,500 hours for FY 2017.

2. Change Small Entity Fees

In accordance with NRC policy, in 2017 the NRC staff conducted a biennial review of small entity fees to determine whether the NRC should change those fees. The NRC staff used the fee methodology, developed in FY 2009, which applies a fixed percentage of 39 percent to the prior 2-year weighted

average of materials users' fees when performing its biennial review. As a result of this review, the upper tier small entity fee would increase from $3,400 to $4,500 and the lower-tier fee would increase from $700 to $900. This would constitute a 43-percent and 50-percent increase, respectively. The NRC staff determined that implementing this increase would have a disproportionate impact upon the NRC's small licensees compared to other licensees, so the NRC staff lowered the increase to 21 percent for the upper-tier and lower-tier fees. The NRC staff chose 21 percent based on the average percentage increase for the prior three biennial reviews of small entity fees. As a result of applying the 21-percent increase to the FY 2015 small entity fees, the NRC staff is now amending the upper-tier small entity fee to $4,100 and amending the lower-tier small entity fee to $850 for FY 2017. The NRC staff believes these fees are reasonable and provide relief to small entities while at the same time recovering from those licensees some of the NRC's costs for activities that benefit them.

3. Amends 10 CFR 171.19(d), To Include Fee Category 3G

The NRC modifies the description under 10 CFR 171.19, ''Payment,'' to include fee category 3G in the description as the annual fee is below $100,000. These licensees in fee category 3G should now be billed annual fees on their anniversary month due to the annual fee being less than $100,000. This change resulted from a decrease in budgeted resources allocated to this fee class for the final rule caused by a decrease in the final appropriation.

Fees Transformation

In a January 30, 2015, paper to the Commission (SECY–15–0015, ''Project Aim 2020 Report and Recommendations'' (ADAMS Accession No. ML15012A594)), the NRC staff recommended that the Office of the Chief Financial Officer (OCFO) undertake an effort to: (1) Simplify how the NRC calculates its fees, (2) improve transparency, and (3) improve the timeliness of the NRC's communications about fee changes. These recommendations were similar to stakeholder comments the staff received during outreach on the NRC's fees and fee development process. In addition, an interoffice steering committee of NRC staff evaluated the current fee process to identify potential; solutions for concerns raised by NRC stakeholders. Based on comments received from the public and input from steering committee members, the staff developed over 40 process and policy improvements to be implemented over the next 4 years that addressed concerns with the current fee process. On August 15, 2016, the Chief Financial Officer (CFO) submitted a paper for Notation Vote (SECY–16–0097 (ADAMS Accession No. ML16194A365)) to the Commission. This memorandum identified 14 process improvements in six categories that the staff would implement in FY 2017 and requested Commission approval to further analyze four improvements as policy issues. The Commission disapproved the policy issues with the exception of a voluntary pilot initiative to explore whether a flat fee structure could be established for routine licensing matters in the area of uranium recovery policy issues. The Commission also directed staff to accelerate the process improvements for future consideration including transition to an electronic billing system.

Currently, 10 of the 14 process improvements for FY 2017 have been completed and the NRC is well-positioned to complete the remaining 4 process improvements by the end of the fiscal year. In addition, 3 of the 9 improvements for FY 2018 have been accelerated and completed. The voluntary pilot project for uranium recovery flat fees and activities to support electronic invoicing are underway. For more information on our fees transformation initiative, please see our License Fees Web site at *https://www.nrc.gov/about-nrc/regulatory/licensing/fees.html.*

III. Opportunities for Public Participation

The NRC published the FY 2017 proposed fee rule in the **Federal Register** on January 3, 2017 (82 FR 8696), for a 30-day public comment period. The rule proposed to amend the licensing, inspection, special project, and annual fees charged to the NRC's applicants and licensees. The public comment period for the proposed rule closed on March 1, 2017.

The NRC also held a public meeting on February 16, 2017, to provide more transparency regarding fees in relation to the budget process and fulfill its commitment to external stakeholders to address NRC program processes and inefficiencies mentioned in the comments submitted for the FY 2016 proposed fee rule. During the public meeting, the NRC received no comments on the FY 2017 proposed fee rule. The public meeting transcript is available as indicated in Section XIV, Availability of Documents, of this document.

IV. Public Comment Analysis

Overview of Public Comments

The NRC received four written comment submissions for the proposed rule. A comment submission for the purpose of this rule is defined as a communication or document submitted to the NRC by an individual or entity with one or more distinct comments addressing a subject or an issue. A comment, on the other hand, refers to a statement made in the submission addressing a subject or issue. In general, the commenters were supportive of the specific proposed regulatory changes, although most commenters expressed concerns about broader fee-policy issues related to transparency and fairness.

The commenters are listed in Table XIX, and are classified as follows: One member of the uranium industry (Wyoming Mining Association (WMA)); one nuclear power plant operator (Exelon); one private citizen; and one industry trade group (Nuclear Energy Institute (NEI)).

TABLE XIX—FY 2017 PROPOSED FEE RULE COMMENTER SUBMISSIONS

Commenter	Affiliation	ADAMS accession No.	Abbreviation
Travis Deti	Wyoming Mining Association	ML17108A265	WMA.
J. Bradley Fewell	Exelon Generation Company, LLC	ML17108A267	Exelon.
Joseph E. Pollock	Nuclear Energy Institute	ML17108A266	NEI.
Kevin Ramsey	Private Citizen	ML17108A264	KR.

Information about obtaining the complete text of the comment submissions is available in Section XIV, ''Availability of Documents,'' of this document.

Public Comments and NRC Responses

The NRC has carefully considered the public comments received. The comments have been organized by topic followed by the NRC response.

A. Uranium Recovery

Comment: The increases for each category of uranium recovery license over the 2016 annual fees exceed 8 percent. This increase exceeds the current rate of inflation and increases in costs from vendors, suppliers, and contractors with which the uranium recovery industry does business. It exceeds annual salary increases for uranium recovery workers as well. Uranium prices have been in overall decline for the past five (5) years. The uranium recovery industry fails to see how increases of this magnitude can be justified. (WMA)

Response: As discussed in the proposed FY 2017 fee rule, the proposed amendments to the annual fees are necessary to comply with OBRA–90, which requires the NRC to recover approximately 90 percent of its annual budget through fees. Because the NRC (by law) must recover approximately 90 percent of its annual budget authority, the NRC cannot take the rate of inflation or other economic indicators into account when deriving the annual fees.

Further, for the FY 2017 final fee rule, the annual fee for non-DOE uranium recovery licensees will remain flat for most licensees. This change from the projected 8 percent increase in the proposed rule is due to a decrease in budgetary resources and an increase in non-DOE 10 CFR part 170 estimated billings. For additional information, refer to the uranium recovery section of this final rule.

No change was made to the final rule in response to this comment.

Comment: It is not clear how the NRC will address the change in workload for this license class when the NRC will lose nearly all of the uranium recovery licenses with the entry of Wyoming as an Agreement State. Per the Fee Work Papers, there are approximately 29 FTE for 9 uranium recovery licensees. Basic In-Situ recovery facilities have seen annual fees increase 80% since FY 2012, and this small licensee class cannot continue to absorb additional losses to the fee base without corresponding NRC resource reductions. (NEI, Exelon)

Response: Specific to Wyoming's request to become an Agreement State, the NRC staff has established a transition team to evaluate the potential impacts and appropriately transition work in the event the NRC approves Wyoming's application. As part of our Wyoming transition initiative, the NRC will review its resource requirements for future budgets and explore alternative methods of developing the fee schedule to support a continued fair and equitable assessment of fees from a smaller set of licensees after Wyoming becomes an Agreement State.

In addition, as part of the fees transformation initiative, the NRC is beginning a voluntary pilot to explore whether a flat fee structure could be established for routine licensing matters in the area of uranium recovery. As part of this pilot the NRC will engage with stakeholders to solicit feedback on the proposed strategy before a final decision is made.

No change was made to the final rule in response to this comment.

Comment: The WMA questions why work on specific projects should increase fees for all licensees. Costs related to specific projects should be recovered through hourly charges. (WMA)

Response: Costs related to specific projects are recovered through hourly charges and do not increase fees for all licensees. The part of the FY 2017 fee rule discussion being questioned by the commenter is only a general description of the business environment affecting the 10 CFR part 170 user fees (*i.e.,* hourly charges). As described in the FY 2017 fee rule, the annual fees are determined after deducting the amount to be recovered through 10 CFR part 170 user fees.

No change was made to the final rule in response to this comment.

Comment: The proposed fee rule contains a 9% annual fee increase for uranium recovery facilities due to, in part, an increase in the budgeted resources to ''support contested hearing activities.'' The NRC should consider modifying the existing policy for treatment of contested hearings, particularly for fee categories comprised of a small number of licensees where imposition of these additional costs are punitive and disadvantage licensees' ability to compete in global markets. The industry supports treating costs associated with contested hearings, for all licensee classes, as non-fee activities. (NEI, Exelon)

Response: Hearing costs are not recovered through 10 CFR part 170 user fees due to longstanding fairness and equity concerns with billing the applicant for the costs of a public hearing. Therefore, the work on these contested hearings must be recouped through annual fees. Hearings are budgeted as our best estimate based on historical expenditures; however, the actual resources expended will vary depending on the number of contentions and the complexity of each contention. Each hearing is different.

Further, for the FY 2017 final fee rule, the annual fee for non-DOE uranium recovery licensees will remain flat for most licensees. This change from the projected 8 percent increase in the proposed rule is due to a decrease in budgetary resources and an increase in non-DOE 10 CFR part 170 estimated billings. For additional information, refer to the uranium recovery section of this final rule.

As part of our Wyoming transition initiative, the NRC will explore alternative methods of developing the fee schedule to support a continued fair and equitable assessment of fees to recover the budgetary resources associated with contested hearings. The alternative methods may include seeking an appropriation off the fee base, developing an alternate fee class structure, or classifying the resources as fee relief. The NRC will evaluate these changes and the associated impacts across the various fee classes and categories in a future fee rule.

No change was made to the final rule in response to this comment.

Comment: Page 8702 of the **Federal Register** document states that uranium recovery licensee fees increased, in part, due to the increased workload for congressional hearings and inquiries. It is inappropriate to seek compensation from any licensee for this activity. The level of NRC resources to support this activity is not transparent. We expect to see the recovery amount for this business line to go down as a result of the removal of this activity. (NEI, Exelon)

Response: OBRA–90 requires the NRC to collect fees for a broad amount of activities necessary to operate the agency including guidance and regulatory infrastructure as well as government compliance activities. Because congressional hearings and inquiries are not a major factor when setting annual fees for the uranium recovery fee class, this language will be deleted from the final rule. This change will not impact the recovery amount or fees assessed.

B. Transparency

Comment: Although the NRC has added some additional information to the work papers supporting the

proposed fee rule, the papers still lack enough detail to precisely determine the specific costs that are being recovered through annual fees. For example, the work papers indicate that several items dominate the contracting portion encompassed by the operating reactor annual fee. However, the work papers provide no information regarding the specific projects driving these contracting numbers, such as the issues being researched, the type of information technology support needed, and the licensing actions anticipated. We encourage the NRC to continue adding detail to the work papers to allow licensees to discern exactly what work their annual fees are funding. (Exelon)

Response: Consistent with prior years, license fees are based on the NRC's budget formulation structure hierarchy of business lines, product lines, and products. The commenter is correct that the work papers do not distinguish these activities on the basis of whether these line items will be recovered through user or annual fees. However, distinguishing these activities would prove unduly burdensome for the NRC to perform this type of analysis for every business line, product line, and product in its budget.

The NRC would not be able to provide specific information on contracts since it is proprietary in nature. However, as part of the fees transformation initiative, project managers are providing enhanced licensee outreach to increase awareness of general contract activities and costs.

No change was made to the final rule in response to this comment.

Comment: While the NRC provided a clear explanation of the difference between international cooperation and assistance activities and how fees are accounted for each, there continues to be a lack of transparency with the benefit provided to the regulated community. The proposed fee rule Table III, ''Fee-Relief Activities'', clearly identifies $13.9 million for international assistance activities. However, to ascertain the international cooperation budgeted activities requires going through each product line to add the budgeted costs. Clear transparency of the cooperation activities budget and a better description of the specific activities and how they benefit the regulated community is needed. This request does not question the overall value of the benefits of assistance and cooperation activities to the safety and security of the world and United States. The split between assistance and cooperation is difficult to ascertain without laborious work. (NEI, Exelon)

Response: The NRC agrees with the comment. In the final rule, the NRC has improved transparency for international cooperation by compiling all such costs in a table in the work papers, which should allow the split between assistance and cooperation activities to be more easily determined by the reader. As stated in the proposed rule, the amount of international activities that the NRC allocated to international fee relief is $13.9 million, which includes international nuclear safety and radioactive source security assistance activities, as well as support for international conventions and treaties, and technical cooperation activities whose benefits range across several classes of licensees and therefore cannot be identified by fee class.

The amount not included under international fee relief activities represents international resources that the NRC assigned to each mission-direct fee class in the work papers. Specifically, these resources represent international cooperation activities that benefit a specific fee class (rather than international assistance activities or technical cooperation activities whose benefits range across several classes of licensees). These fee-recoverable cooperation activities provide direct input to the NRC's regulations and the NRC's oversight of its licensees and, therefore, benefit a group of NRC licensees. For example, international cooperative activities involve sharing information, knowledge, and technical expertise with the NRC's international regulatory counterparts. These international cooperative activities enhance the NRC's regulatory programs by providing direct input into the NRC's regulation and oversight of its licensees. International cooperation activities also provide other benefits to NRC licensees, such as collaborative research that is relevant to the NRC's regulatory programs. The NRC continuously assesses and, where relevant, incorporates international operating experience and research insights into the NRC's domestic regulatory program. As an example of the relevance of international cooperation work to the NRC's nuclear safety mission, power reactor licensees benefit from international efforts to exchange information on operational events, regulatory experience, and expertise on construction, startup, and the operation of nuclear power plants.

Changes were made to the final rule work papers in response to this comment.

Comment: While detailed calculations of the annual fee are provided, there is a lack of detail related to the basis behind 10 CFR part 170 fees. In the interest of transparency, NRC should provide the data or assumptions used to make these estimates. For example, historical information could be provided for average inspection hours for a licensee class, estimated number of staff hours for license reviews, and hours spent on pre-application activities for small modular and advanced reactors. This information would provide stakeholders with the ability to analyze the efficiency and effectiveness of NRC's review. (NEI, Exelon)

Response: The NRC estimates the amount of 10 CFR part 170 fees based on established fee methodology guidelines (42 FR 22149; May 2, 1977), which specified that the NRC has the authority to recover the full cost of providing services to identifiable beneficiaries. As in previous years, the NRC applied longstanding principles to calculate the 10 CFR part 170 estimates based on the analysis of financial data. The data analyzed to devise the 10 CFR part 170 estimate included: (1) Four quarters of the most recent billing data (hourly rate invoice data); (2) actual contractual work charged (prior period data) to develop contract work estimates; and (3) the number of FTE hours charged multiplied by the NRC professional hourly rate. These factors, along with workload projections, are used by the NRC to determine the 10 CFR part 170 estimated charges. Because the fee calculation worksheets used to develop the 10 CFR part 170 estimates involve thousands of calculations, it would be impractical for the NRC to provide details on every calculation.

Unrelated to the calculation of 10 CFR part 170 estimates, the NRC is currently developing estimates for services to be posted on our Web site as part of our Fee Transformation initiative.

No change was made to the final rule in response to this comment.

C. Workload/Non-Mission-Direct Resources

Comment: The hourly rate remains very high especially in comparison to the hourly rates of consultants working for the uranium recovery industry. (WMA)

Response: To the extent the commenter believes that the NRC's hourly rate should be comparable to the hourly rate for uranium-recovery consultants, the NRC disagrees with this comment. All fees assessed to licensees and applicants by the NRC must conform to OBRA–90 and IOAA requirements, in contrast to industry consultants working for the uranium recovery industry. Under the IOAA, the

NRC must recover its full costs of providing specific regulatory benefits to identifiable applicants and licensees. In so doing, the NRC establishes an hourly rate for its work. Consistent with the IOAA, the NRC determines its hourly rate by dividing the sum of recoverable budgeted resources for: (1) Mission-direct program salaries and benefits; (2) mission-indirect program support; and (3) agency support—which includes corporate support and the IG. The mission-direct FTE hours are the product of the mission-direct FTE multiplied by the hours per direct FTE. The only budgeted resources excluded from the hourly rate are those for contract activities related to mission-direct and fee-relief activities.

No change was made to the final rule in response to this comment.

Comment: Of a 2080 hour working year, for 2017 only 1,500 of those hours are deemed to be spent on mission-direct work which is considered to be an improvement over Fiscal Year 2016 when only 1,440 hours were deemed spent on mission-direct work. The remaining hours (the 580 hours in Fiscal Year 2016 spent on non-mission-direct work) are . . . charged to annual leave, sick leave, holidays, training and general administration tasks.

The WMA considers the proportion of hours (28%) spent on non-mission-direct work to be excessive and that a much smaller portion of time should be devoted to non-mission-direct work. (WMA)

Response: The NRC uses an estimate of the number of direct hours per FTE to calculate the hourly rate used in 10 CFR part 170 billing. The OMB's Circular A–25, ''User Charges,'' does not specifically address the number of hours to assume per FTE in calculating fees, but does emphasize that agency fees should reflect the full cost of providing services to identifiable beneficiaries. In addition, Title V of the United States Code establishes holidays, annual leave and sick leave amounts government wide for all employees.

In the final fee rule for FY 2005 (70 FR 30526, May 26, 2005), the NRC revised its estimate of the number of mission-direct hours per FTE to use a realistic estimate based on time and labor data for program employees who perform activities directly associated with the programmatic mission of the NRC. The NRC periodically reviews time and labor data to assess changes in the average number of productive hours from year to year and determines a realistic estimate of direct hours per FTE based on the most recent data. The estimate does not include time for administration, training, and other activities a mission-direct program FTE may perform that, while relevant to consider for certain costing purposes, would more accurately be considered overhead rather than mission-direct time for purposes of calculating a rate per hour of direct activities. When the NRC calculates the fees required to recover the budget enacted by Congress, this estimate of mission-direct hours per FTE is used to calculate the hourly rate.

The estimate of 1,500 hours per FTE used in the fee rule calculation for FY 2017 was based on an analysis of actual time and labor data from FY 2016. Use of an updated, realistic estimate of mission-direct hours per FTE helps ensure that the hourly rate accurately reflects the current cost of providing 10 CFR part 170 services, allowing the NRC to more fully recover the costs of these services through 10 CFR part 170 fees.

No change was made to the final rule in response this comment.

D. Decreasing Number of Licensees in Fee Class

Comment: The FY 2017 proposed fee rule continues to provide fee relief for fuel cycle facilities. However, Page 8701 states that the fuel facilities fee class [annual fee] will be adjusted in the final rule with the expected departure of a current licensee. The loss of this licensee has been known for over one year and represents approximately 5% of the total annual fees collected from fuel facilities. It is our expectation that NRC has appropriately planned for this license termination and will decrease the licensing and oversight resources needed and the overall budget in the fuel facilities business line, rather than force operating facilities to absorb these annual fees. Therefore, this closure should not result in an increased fee burden to the remaining licensees. (NEI, Exelon)

Response: The NRC removes licensees from the fuel facilities fee class after the licensee permanently ceases principal activities. The commenter is correct that the NRC was aware that the referenced licensee had informed the NRC that they were planning to cease principal activities. However, the licensee did not cease principal activities until late in the first quarter of fiscal year 2017, after the proposed fee rule had been issued. At that point, the licensee was officially placed in decommissioning status and will be assessed a prorated annual fee according to our regulations. Notwithstanding, the policy of the agency remains that the portion of the annual fee not assessed to the licensee leaving the fee class will be distributed to the remaining fuel facilities licensees. However, the NRC will continue to analyze changes to workload, budget resources and the composition of fee classes to support a fair and equitable fee setting process.

No change was made to the final rule in response to this comment.

E. FY 2017 Congressional Appropriation

Comment: The proposed FY 2017 fee rule, based on right sizing agency activities and additional re-baselining reductions, represents a move in the right direction by lowering excessive annual fees, some significantly, for a majority of licensees. Adopting a fee structure based on FY 2016 spending levels would be a move backwards and would ignore the progress the agency has made to appropriately prioritize its work and staff size. Therefore, if the NRC receives a continuing resolution for the remainder of the year, the FY 2017 proposed rule should be considered a ceiling for NRC spending. (NEI, Exelon)

Response: OBRA–90 requires that the NRC collect approximately 90 percent of its budget authority through fees by the end of the fiscal year, and the NRC must set its fees in accordance with its budgetary resources as this practice ensures that NRC fees assessed bear a reasonable relationship to the cost of NRC services. This rule is based upon the Consolidated Appropriations Act, 2017 (Pub. L. 115–31), dated May 5, 2017.

No change was made to the final rule in response to this comment.

F. Invoicing

Comment: There have been some recent improvements regarding invoicing; however, problems remain. In addition, there is no predictability for budgeting purposes regarding the magnitude of these invoices in regards to the review of a given submittal. The uranium recovery industry needs, for budgeting purposes, to be able to estimate the total value of future review invoices for a given submittal. Members of the uranium recovery industry have no idea of the magnitude of the quarterly review invoices until they arrive and must be paid. This creates a difficult situation in the form of large, unanticipated expenses for uranium recovery operators. If the agency as part of its completeness review were to provide an approximate and non-binding estimate of cost to compete the review of a given submittal it would be very helpful to uranium recovery operators. (WMA)

Response: The NRC currently provides, by request, preliminary estimates of costs incurred on a biweekly basis to licensees. The estimates include all (10 CFR part 170)

costs that accumulated for license fee billing during the previous NRC pay period. The estimates include NRC staff names with associated number of hours worked as well as contractor names associated with contract costs, which offer licensees additional detail. These estimates may assist licensees in budget planning and their preparation to receive their next quarterly invoice. Licensees may request to receive biweekly estimates by sending an email to *FEES.Resource@nrc.gov* with docket number(s) and licensee email address(es) to which the estimates should be sent. In addition, the uranium recovery staff have offered to meet with licensees and applicants on a quarterly basis to forecast upcoming workload so that licensees and applicants have an idea of the work that will be included on future invoices. Lastly, the NRC staff has posted on its public Web site estimates of the cost of major uranium recovery licensing actions. For more information, please see our Licenses Fees Web site at *https://www.nrc.gov/about-nrc/regulatory/licensing/fees.html.*

No change was made to the final rule in response to this comment.

Comment: Exelon applauds the fee development process improvements that the NRC has thus far implemented. To that end, we encourage the NRC to continue striving for additional efficiency gains, such as electronic invoicing. The NRC should explore immediate, incremental steps towards electronic invoicing short of an entire system upgrade (which the NRC is not planning to implement until FY 2020). This could include, for example, automatically emailing copies of the paper invoices as soon as those invoices are mailed to the licensee. Even that small step would benefit licensees by providing more timely invoices. (Exelon)

Response: The NRC focused on the improvement initiatives currently underway that include improving billing data, accuracy, and electronic invoicing. The NRC issues more than 5,000 invoices per year. Emailing invoices to licensees with the current information technology systems and configuration would be an intensive manual process requiring substantial resources.

No change was made to the final rule in response to this comment.

Comment: WMA continues to be concerned about the agency's invoicing process.

In its comments dated May 4, 2016 on the Request for Information—Fees Development and Communications—(**Federal Register** Volume 81, Number. 55/Tuesday, March 22, 2016/Notices) the WMA commented extensively on invoicing and concluded:

The WMA believes that a substantial problem with the agency's invoicing is the lack of predictability in the invoice amounts. This could be mitigated to some extent by flat fee invoicing for some items however for others, it would require that the agency prepare a nonbinding estimate of cost to complete the review. (WMA)

Response: As previously noted, licensees may request to receive biweekly estimates by sending an email to *FEES.Resource@nrc.gov* with docket number(s) and licensee email address(es) to which the estimates should be sent. Also, the NRC will explore how to display more detailed invoice information. It should be noted that contractor information in most cases is considered proprietary but we will work with our contractors to determine what information can be released.

Additionally, as directed in SRM–SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' dated October 19, 2016, (ADAMS Accession No. ML16293A902) the NRC staff is exploring whether a flat fee structure could be established for routine licensing matters in the area of uranium recovery. In addition, staff is also evaluating the level of detail to be provided in invoices.

No change was made to the final rule in response to this comment.

Comment: The administrative change from the FY 2015 final fee rule to revise the assessment of administrative time for project managers by adding a 6% Project Manager/Resident Inspector allocation continues to be an excessive burden on licensees that double, and in some instances triple charge, for project manager work. This change intended to allocate overhead costs to each licensee based on direct time to each docket to ensure that a licensee's overhead costs are proportional to the regulatory services rendered by the NRC. While we understand that this is a temporary charge, it continues to be a hidden extra fee for the licensee for non-direct work activities when these activities are already being fully billed as cost recovery items that project managers charge for work on a specific task. For example, some licensees have received invoices for project manager time on the same activity being triple charged under (1) Project management general work cost activity codes (CACs); (2) technical CAC; and (3) the 6% Project Manager/Resident Inspector allocation. The 6% allocation on all NRC staff hours effectively increases the proposed hourly rate from $267 to $283. We advise consistency with regards to project manager 10 CFR part 170 invoicing and awareness training for project managers of the 6% allocation to avoid multiple billings for the same work. (NEI, Exelon)

Response: To the extent the commenter believes that the NRC is double- and triple- billing licensees, the NRC disagrees with this comment. The NRC staff charges to direct billable CACs only when that work benefits a single, identifiable licensee. The project manager (PM)/resident inspector allocation recovers the costs for all PMs and senior resident inspectors (SRIs) that are not directly attributable to a single licensee, but rather benefit the entire class of licensees (*e.g.,* indirect activities such as PM technical support to the regional offices, PM training and attendance at conferences, PM participation in working groups). When a PM or SRI supports work under this allocation, the PM is not directly billing a licensee. This activity is pooled and distributed to all licensees as 6 percent of the direct labor charges provided by agency staff. Because these activities ultimately benefit all licensees, the agency has instituted average cost recovery to recover from all licensees for these activities.

As part of the fees transformation direction from the Commission, SRM–SECY–16–0097: Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule (ML16293A902) the Commission directed staff to review the 2015 fee rule revised methodology of charging overhead time for project managers and resident inspectors and modify it for more clarity. As part of this initiative, the NRC will consider alternate strategies for recovery of the resources allocated to administrative time for project managers and resident inspectors and develop a new approach to be implemented by October 2018.

No change was made to the final rule in response to this comment.

G. Predictability

Comment: Industry appreciates the move in the right direction to publish the proposed FY 2017 fee rule earlier in the year. However, greater transparency and predictability in fee policy could be realized if the NRC published the proposed rule in the first quarter of the fiscal year and the final fee rule in the second quarter or early in the third quarter of the fiscal year. Accelerating the rulemaking schedule would not appear to be problematic for the NRC because the Congressional Budget Justification (CBJ) is publicly-released

coinciding with transmittal of the President's Budget Request to Congress (*i.e.,* in February before the fiscal year begins), and the CBJ currently provides a fee recovery estimate. Early publication would allow licensees to plan, adjust budgets and manage cash flow. (NEI, Exelon)

Response: OBRA–90 requires that the NRC collect approximately 90 percent of its budget authority through fees by the end of the fiscal year. The NRC must set its fees in accordance with its final budget authority. Further, the annual appropriation cycle places additional constraints upon the NRC. Even though the NRC does not know the amount of fees it will need to collect until after it receives its annual appropriation from Congress, the NRC starts the rulemaking process in the preceding summer. The NRC believes that reliance on the most up-to-date financial data available in determining fees, using the CBJ (adjusted for fact-of-life-changes) supports compliance with the requirements of OBRA–90. This practice ensures that NRC fees assessed bear a reasonable relationship to the cost of NRC services. The NRC recognizes that the issuance of the rule may not coincide with budget cycles of industry; however, the NRC must promulgate a notice-and-comment rule based on the most accurate data available regarding the cost of NRC services in the context of the NRC's budget for a given fiscal year. For FY 2017, the NRC published the proposed fee rule in January; two months earlier than in FY 2016.

No change was made to the final rule in response to this comment.

H. Miscellaneous

Comment: The Schedule of Materials Fees has several errors and omissions in the Program Codes listed for Special Nuclear Material.

—Category 1A(1)(a) should reference Program Code 21213, not 21130.
—Category 1A(2)(a) should include Program Code 21240.
—Category 1A(2)(b) should reference Program Code 21205.
—Category 1A(2)(c) should reference Program Codes 21130 and 31133. (KR)

Response: The NRC agrees with this comment. The Schedule of Materials Fees is corrected in this final rule to reflect the correct program codes with the following exception:

For Category 1A(2)(c), program code 31133 is not in our system. We assume the commenter meant program code 21133. The NRC added program code 21133 to Category 1A(2)(c).

Comment: We continue to be concerned that an excessive portion of the budget is funding corporate support and non-mission-direct activities. NRC has cumulatively reduced budgeted amounts for mission direct and mission indirect expenditures by 6.5%. That represents a move in the right direction from re-baselining agency activities. However, the budget for agency support increased by 3%. The proposed fee rule Table II, ''Hourly Rate Calculation,'' identifies $340.5 million for mission direct program activities and $136.7 million for mission indirect program support, which represents 60% of the total adjusted amount to be recovered through fees ($801.4 million). Yet, the portion of the budget allocated to corporate support is $324.2 million and represents 40% of budgeted resources. Agency support, which is a key factor in both the hourly rate and annual fee calculations, appears to be disproportionately large with respect to the resources allocated for mission direct and mission indirect activities. These overhead costs not only remain excessive compared to its peer agencies, but have also increased from FY 2016. In order to maintain credibility, NRC must focus their resources on mission critical activities that have a direct correlation with maintaining public health and safety and must reduce overhead costs. (NEI, Exelon)

Response: The NRC agrees that the proportion of corporate support and mission support resources, compared to program resources, is one factor to consider in assembling a budget that accomplishes NRC's mission in an effective and efficient manner.

The NRC notes that, in calculating the percentage of mission-direct program activities, the commenter does not take into account all mission-direct resources contained in the total budget authority presented in the FY 2017 proposed fee rule. The $340.5 million referenced by the commenter includes only mission-direct salaries and benefits—it does not include the mission-direct amount for contract support, which is an additional $125.3 million. Although not included within the hourly rate, mission-direct contract support is a significant component of the direct costs within the agency's total budget authority. Total mission-direct program activities in the proposed rule—including salaries, benefits, and contract support—equaled $465.8 million. Further, the $136.7 million that the NRC budgeted for mission-indirect program support in the proposed rule brings the NRC's total budgeted mission costs to $602.5 million, or 65 percent of the total budget authority less excluded fee items. The remaining 35 percent for Agency Support in the proposed rule included resources for the NRC's Office of the Inspector General, which is not included when calculating corporate support.

No change was made to the final rule in response to this comment.

I. Comments on Matters Not Related to This Rulemaking

Some comments suggested that the NRC implement a number of recommendations to streamline the regulatory process, review the changing technical guidance to licensees, and consider risk when executing regulatory oversight activities.

All of these matters are outside the scope of this rulemaking. The primary purpose of the NRC's annual fee recovery rulemaking is to update the NRC's fee schedules to recover approximately 90 percent of the appropriations that the NRC received for the current fiscal year, and to make other necessary corrections or appropriate changes to specific aspects of the NRC's fee regulations in order to ensure compliance with OBRA–90, as amended.

The NRC takes very seriously the importance of examining and improving the efficiency of its operations and the prioritization of its regulatory activities. Recognizing the importance of continuous reexamination and improvement of the way the agency does business, the NRC has undertaken, and continues to undertake, a number of significant initiatives aimed at improving the efficiency of NRC operations and enhancing the agency's approach to regulating.

V. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[8] the NRC has prepared a Regulatory Flexibility Analysis (RFA) relating to this final rule. The RFA is available as indicated in Section XIV, Availability of Documents, of this document.

VI. Regulatory Analysis

Under OBRA–90, the NRC is required to recover approximately 90 percent of its budget authority in FY 2017. The NRC established fee methodology guidelines for 10 CFR part 170 in 1978, and established additional fee methodology guidelines for 10 CFR part 171 in 1986. In subsequent rulemakings, the NRC has adjusted its fees without changing the underlying principles of its fee policy to ensure that the NRC

[8] 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 847 (1996).

continues to comply with the statutory requirements for cost recovery in OBRA–90 and the AEA.

In this rulemaking, the NRC continues this long-standing approach. Therefore, the NRC did not identify any alternatives to the current fee structure guidelines and did not prepare a regulatory analysis for this rulemaking.

VII. Backfitting and Issue Finality

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and that a backfit analysis is not required. A backfit analysis is not required because these amendments do not require the modification of, or addition to, systems, structures, components, or the design of a facility, or the design approval or manufacturing license for a facility, or the procedures or organization required to design, construct, or operate a facility.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883). The NRC requests comment on this final rule with respect to the clarity and effectiveness of the language used.

IX. National Environmental Policy Act

The NRC has determined that this rule will amend NRC's administrative requirements in 10 CFR part 170 and 10 CFR part 171. Therefore, this action is categorically excluded from needing environmental review as described in 10 CFR 51.22(c)(1). Consequently, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

X. Paperwork Reduction Act

This final rule does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act of 1996 (5 U.S.C. 801–808). The Office of Management and Budget has found it to be a major rule as defined in the Congressional Review Act.

XII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC proposes to amend the licensing, inspection, and annual fees charged to its licensees and applicants, as necessary, to recover approximately 90 percent of its budget authority in FY 2017, as required by OBRA–90, as amended. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XIII. Availability of Guidance

The Small Business Regulatory Enforcement Fairness Act requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. The NRC, in compliance with the law, prepared the ''Small Entity Compliance Guide'' for the FY 2017 final fee rule. The compliance guide was developed when the NRC completed the small entity biennial review for FY 2017. This document is available as indicated in Section XIV, Availability of Documents, of this document.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./web link
SECY–16–0009, ''Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities,'' dated February 9, 2016.	ML16104A158.
SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' dated August 15, 2016.	ML16194A365.
SRM–SECY–16–0097: Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule.	ML16293A902.
FY 2017 Final Rule Work Papers	ML17164A283.
FY 2017 Regulatory Flexibility Analysis	ML16340A151.
FY 2017 U.S. Nuclear Regulatory Commission Small Entity Compliance Guide	ML16340A149.
NUREG–1100, Volume 32, ''Congressional Budget Justification: Fiscal Year 2017'' (February 2016).	*https://www.nrc.gov/docs/ML1603/ML16036A086.pdf.*
NRC Form 526, Certification of Small Entity Status for the Purposes of Annual Fees Imposed under 10 CFR Part 171.	*http://www.nrc.gov/reading-rm/doc-collections/forms/nrc526.pdf.*
FY 2017 Proposed Fee Rule Comment Submissions	ML17108A263.
FY 2017 Proposed Fee Rule	ML16337A270.
FY 2017 Proposed Rule Work Papers	ML16358A648.
Meeting Summary Notes for the Public Meeting on the FY 2017 Proposed Fee Rule held on February 16, 2017.	ML17062A797.
SECY–05–0164, ''Annual Fee Calculation Method,'' dated September 15, 2005	ML052580332.
OMB's Circular A–25, ''User Charges''	*https://obamawhitehouse.archives.gov/omb/circulars_a025/.*
Consolidated Appropriations Act, 2017 (Pub. L. 115–31)	*https://www.congress.gov/bill/115th-congress/house-bill/244.*

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 170 and 171.

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 1. The authority citation for part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

■ 2. Revise § 170.20 to read as follows:

§ 170.20 Average cost per professional staff-hour.

Fees for permits, licenses, amendments, renewals, special projects, 10 CFR part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 will be calculated using the professional staff-hour rate of $263 per hour.

■ 3. In § 170.21, in the table, revise fee category K. to read as follows:

§ 170.21 Schedule of fees for production or utilization facilities, review of standard referenced design approvals, special projects, inspections, and import and export licenses.

* * * * *

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of fees	Fees [1] [2]
* * * * * * *	
K. Import and export licenses:	
Licenses for the import and export only of production or utilization facilities or the export only of components for production or utilization facilities issued under 10 CFR part 110.	
1. Application for import or export of production or utilization facilities [4] (including reactors and other facilities) and exports of components requiring Commission and Executive Branch review, for example, actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	$18,400
2. Application for export of reactor and other components requiring Executive Branch review, for example, those actions under 10 CFR 110.41(a).	
Application—new license, or amendment; or license exemption request	9,200
3. Application for export of components requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	4,500
4. Application for export of facility components and equipment not requiring Commission or Executive Branch review, or obtaining foreign government assurances.	
Application—new license, or amendment; or license exemption request	4,500
5. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms or conditions or to the type of facility or component authorized for export and, therefore, do not require in-depth analysis or review or consultation with the Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment to license	2,600

[1] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under § 2.202 of this chapter or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 50.12, 10 CFR 73.5) and any other sections in effect now or in the future, regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect when the service was provided.

* * * * * * *

[4] Imports only of major components for end-use at NRC-licensed reactors are authorized under NRC general import license in 10 CFR 110.27.

* * * * * * *

■ 4. In § 170.31, revise the table to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2] [3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U-235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [Program Code(s): 21213]	Full Cost.
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [Program Code(s): 21210]	Full Cost.
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations [Program Code(s): 21240, 21310, 21320]	Full Cost.
(b) Gas centrifuge enrichment demonstration facilities [Program Code(s): 21205]	Full Cost.
(c) Others, including hot cell facilities [Program Code(s): 21130, 21133]	Full Cost.
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [Program Code(s): 23200].	Full Cost.
C. Licenses for possession and use of special nuclear material of less than a critical mass as defined in § 70.4 in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.[4] Application [Program Code(s): 22140].	$1,200.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A.[4] Application [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310].	$2,400.
E. Licenses or certificates for construction and operation of a uranium enrichment facility [Program Code(s): 21200]	Full Cost.
F. Licenses for possession and use of special nuclear material greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities.[4] [Program Code(s): 22155].	Full Cost.
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal. [Program Code(s): 11400]	Full Cost.
(2) Licenses for possession and use of source material in recovery operations such as milling, *in-situ* recovery, heap-leaching, ore buying stations, ion-exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities [Program Code(s): 11100]	Full Cost.
(b) Basic *In Situ* Recovery facilities [Program Code(s): 11500]	Full Cost.
(c) Expanded *In Situ* Recovery facilities [Program Code(s): 11510]	Full Cost.
(d) *In Situ* Recovery Resin facilities [Program Code(s): 11550]	Full Cost.
(e) Resin Toll Milling facilities [Program Code(s): 11555]	Full Cost.
(f) Other facilities [Program Code(s): 11700]	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [Program Code(s): 11600, 12000].	Full Cost.
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [Program Code(s): 12010].	Full Cost.
(5) Licenses that authorize the possession of source material related to removal of contaminants (source material) from drinking water [Program Code(s): 11820].	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding.[6] [7] [8] Application [Program Code(s): 11210].	$1,200.
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. Application [Program Code(s): 11240].	$2,100.
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. Application [Program Codes(s): 11230, 11231].	$2,600.
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. Application [Program Code(s): 11710].	$2,500.
F. All other source material licenses. Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	$2,500.
3. Byproduct material:	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Application [Program Code(s): 03211, 03212, 03213].	$12,300.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Application [Program Code(s): 03214, 03215, 22135, 22162].	$3,400.
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Application [Program Code(s): 02500, 02511, 02513].	$4,900.
D. [Reserved]	N/A.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units). Application [Program Code(s): 03510, 03520].	$3,000.
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03511].	$6,200.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2 3]
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03521].	$58,700.
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03254, 03255, 03257].	$6,300.
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03250, 03251, 03252, 03253, 03256].	$9,400.
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03240, 03241, 03243].	$1,900.
K. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03242, 03244].	$1,100.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5.	
(1) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–19.	
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 20 or more. Application [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623]	$5,200.
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution. Application [Program Code(s): 03620].	$6,700.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and.	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4.A., 4.B., and 4.C. Application [Program Code(s): 03219, 03225, 03226].	$6,900.
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Application [Program Code(s): 03310, 03320].	$3,000.
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[9] Application [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03130, 03140, 03220, 03221, 03222, 03800, 03810, 22130].	$3,300.
Q. Registration of a device(s) generally licensed under part 31 of this chapter. Registration	$500.
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[5]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4) or (5) but less than or equal to 10 times the number of items or limits specified. Application [Program Code(s): 02700].	$2,400.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5). Application [Program Code(s): 02710].	$2,400.
S. Licenses for production of accelerator-produced radionuclides. Application [Program Code(s): 03210]	$13,400.
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. Application [Program Code(s): 03231, 03233, 03236, 06100, 06101].	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03234].	$6,500.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03232].	$4,700.
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. Application [Program Code(s): 03110, 03111, 03112].	$4,300.
B. Licenses for possession and use of byproduct material for field flooding tracer studies. Licensing [Program Code(s): 03113].	Full Cost.
6. Nuclear laundries:	

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2 3]
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. Application [Program Code(s): 03218].	$21,000.
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Application [Program Code(s): 02300, 02310].	$10,500.
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[10] Application [Program Code(s): 02110].	$8,200.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. Application [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160].	$5,200.
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. Application [Program Code(s): 03710].	$2,400.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution. Application—each device.	$5,100.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices. Application—each device.	$8,500.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution. Application—each source.	$5,000.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel. Application—each source.	$1,000.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	Full Cost.
2. Other Casks	Full Cost.
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators.	
Application	$4,000.
Inspections	Full Cost.
2. Users.	
Application	$4,000.
Inspections	Full Cost.
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices).	Full Cost.
11. Review of standardized spent fuel facilities	Full Cost.
12. Special projects: Including approvals, pre-application/licensing activities, and inspections. Application [Program Code: 25110]	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance.	Full Cost.
B. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including MMLs. Application [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200].	Full Cost.
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, regardless of whether or not the sites have been previously licensed.	Full Cost.
15. Import and Export licenses: Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, and the export only of heavy water, or nuclear grade graphite (fee categories 15.A. through 15.E.).	
A. Application for export or import of nuclear materials, including radioactive waste requiring Commission and Executive Branch review, for example, those actions under 10 CFR 110.40(b). Application—new license, or amendment; or license exemption request.	$18,400.
B. Application for export or import of nuclear material, including radioactive waste, requiring Executive Branch review, but not Commission review. This category includes applications for the export and import of radioactive waste and requires NRC to consult with domestic host state authorities (i.e., Low-Level Radioactive Waste Compact Commission, the U.S. Environmental Protection Agency, etc.). Application—new license, or amendment; or license exemption request.	$9,200.
C. Application for export of nuclear material, for example, routine reloads of low enriched uranium reactor fuel and/or natural uranium source material requiring the assistance of the Executive Branch to obtain foreign government assurances. Application—new license, or amendment; or license exemption request.	$4,500.
D. Application for export or import of nuclear material not requiring Commission or Executive Branch review, or obtaining foreign government assurances. Application—new license, or amendment; or license exemption request.	$4,500.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2] [3]
E. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign government authorities. Minor amendment.	$2,600.
Licenses issued under part 110 of this chapter for the import and export only of Category 1 and Category 2 quantities of radioactive material listed in appendix P to part 110 of this chapter (fee categories 15.F. through 15.R.).	
Category 1 (Appendix P, 10 CFR Part 110) Exports:	
F. Application for export of appendix P Category 1 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)) and to obtain government-to-government consent for this process. (For additional consent see 15.I.). Application—new license, or amendment; or license exemption request.	$14,500.
G. Application for export of appendix P Category 1 materials requiring Executive Branch review and to obtain government-to-government consent for this process. For additional consents see 15.I. Application—new license, or amendment; or license exemption request.	$7,900.
H. Application for export of appendix P Category 1 materials and to obtain one government-to-government consent for this process. For additional consents see 15.I. Application—new license, or amendment; or license exemption request.	$3,900.
I. Requests for each additional government-to-government consent in support of an export license application or active export license. Application—new license, or amendment; or license exemption request.	$300.
Category 2 (Appendix P, 10 CFR Part 110) Exports:	
J. Application for export of appendix P Category 2 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)). Application—new license, or amendment; or license exemption request.	*$14,500.*
K. Applications for export of appendix P Category 2 materials requiring Executive Branch review. Application—new license, or amendment; or license exemption request.	$7,900.
L. Application for the export of Category 2 materials. Application—new license, or amendment; or license exemption request.	$3,200.
M. [Reserved]	N/A.
N. [Reserved]	N/A.
O. [Reserved]	N/A.
P. [Reserved]	N/A.
Q. [Reserved]	N/A.
Minor Amendments (Category 1 and 2, Appendix P, 10 CFR Part 110, Export):	
R. Minor amendment of any active export license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign authorities. Minor amendment.	*$1,300.*
16. Reciprocity: Agreement State licensees who conduct activities under the reciprocity provisions of 10 CFR 150.20. Application.	$1,800.
17. Master materials licenses of broad scope issued to Government agencies: Application [Program Code(s): 03614]	Full Cost.
18. Department of Energy.	
A. Certificates of Compliance. Evaluation of casks, packages, and shipping containers (including spent fuel, high-level waste, and other casks, and plutonium air packages).	Full Cost.
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	Full Cost.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession-only licenses; issuances of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses, except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee category 1.C. only.

(b) *Licensing fees.* Fees for reviews of applications for new licenses, renewals, and amendments to existing licenses, pre-application consultations and other documents submitted to the NRC for review, and project manager time for fee categories subject to full cost fees are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment, unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in fee categories 9.A. through 9.D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended.

[4] Licensees paying fees under categories 1.A., 1.B., and 1.E. are not subject to fees under categories 1.C., 1.D. and 1.F. for sealed sources authorized in the same license, except for an application that deals only with the sealed sources authorized by the license.

[5] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[6] Licensees subject to fees under fee categories 1.A., 1.B., 1.E., or 2.A. must pay the largest applicable fee and are not subject to additional fees listed in this table.

[7] Licensees paying fees under 3.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[8] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[9] Licensees paying fees under 3.N. are not subject to paying fees under 3.P. for calibration or leak testing services authorized on the same license.

[10] Licensees paying fees under 7.B. are not subject to paying fees under 7.C. for broad scope license licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 5. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

■ 6. In § 171.15, revise paragraphs (b)(1), (b)(2) introductory text, (c)(1), (c)(2) introductory text, (d)(1) introductory text, (d)(2) and (3), and (f) to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

* * * * *

(b)(1) The FY 2017 annual fee for each operating power reactor which must be collected by September 30, 2017, is $4,496,000.

(2) The FY 2017 annual fees are comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee, and associated additional charges (fee-relief adjustment). The activities comprising the spent storage/reactor decommissioning base annual fee are shown in paragraphs (c)(2)(i) and (ii) of this section. The activities comprising the FY 2017 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2017 base annual fee for operating power reactors are as follows:

* * * * *

(c)(1) The FY 2017 annual fee for each power reactor holding a 10 CFR part 50 license that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is $188,000.

(2) The FY 2017 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee (which is also included in the operating power reactor annual fee shown in paragraph (b) of this section) and a fee-relief adjustment. The activities comprising the FY 2017 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2017 spent fuel storage/reactor decommissioning re-baselined annual fee are:

* * * * *

(d)(1) The fee-relief adjustment allocated to annual fees includes a surcharge for the activities listed in paragraph (d)(1)(i) of this section, plus the amount remaining after total budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section are reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section for a given fiscal year, annual fees will be reduced. The activities comprising the FY 2017 fee-relief adjustment are as follows:

* * * * *

(2) The total FY 2017 fee-relief adjustment allocated to the operating power reactor class of licenses is an $11,074,000 fee-relief surcharge, not including the amount allocated to the spent fuel storage/reactor decommissioning class. The FY 2017 operating power reactor fee-relief adjustment to be assessed to each operating power reactor is approximately a $111,863 fee-relief surcharge. This amount is calculated by dividing the total operating power reactor fee-relief surplus adjustment, $11,074,000, by the number of operating power reactors (99).

(3) The FY 2017 fee-relief adjustment allocated to the spent fuel storage/reactor decommissioning class of licenses is a $467,500 fee-relief assessment. The FY 2017 spent fuel storage/reactor decommissioning fee-relief adjustment to be assessed to each operating power reactor, each power reactor in decommissioning or possession-only status that has spent fuel onsite, and to each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is a $3,832 fee-relief assessment. This amount is calculated by dividing the total fee-relief adjustment costs allocated to this class by the total number of power reactor licenses, except those that permanently ceased operations and have no fuel onsite, and 10 CFR part 72 licensees who do not hold a 10 CFR part 50 license.

* * * * *

(f) The FY 2017 annual fees for licensees authorized to operate a research or test (non-power) reactor licensed under 10 CFR part 50, unless the reactor is exempted from fees under § 171.11(a), are as follows:

Research reactor	$81,400
Test reactor	81,400

■ 7. In § 171.16, revise paragraphs (c) and (d) and (e) introductory text to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section, in addition to 10 CFR part 72 licenses, may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in the following table. Failure to file a small entity certification in a timely manner could result in the receipt of a delinquent invoice requesting the outstanding

balance due and/or denial of any refund that might otherwise be due. The small entity fees are as follows:

	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing (Average gross receipts over last 3 completed fiscal years):	
$485,000 to $7 million	$4,100
Less than $485,000	850
Small Not-For-Profit Organizations (Annual Gross Receipts):	
$485,000 to $7 million	4,100
Less than $485,000	850
Manufacturing Entities that Have An Average of 500 Employees or Fewer:	
35 to 500 employees	4,100
Fewer than 35 employees	850
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 49,999	4,100
Fewer than 20,000	850
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Fewer	
35 to 500 employees	4,100
Fewer than 35 employees	850

(d) The FY 2017 annual fees are comprised of a base annual fee and an allocation for fee-relief adjustment. The activities comprising the FY 2017 fee-relief adjustment are shown for convenience in paragraph (e) of this section. The FY 2017 annual fees for materials licensees and holders of certificates, registrations, or approvals subject to fees under this section are shown in the following table:

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1] [2] [3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [Program Code(s): 21213]	$7,700,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [Program Code(s): 21210]	2,790,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities	
(a) Facilities with limited operations [Program Code(s): 21240, 21310, 21320]	$0
(b) Gas centrifuge enrichment demonstration facilities [Program Code(s): 21205]	1,507,000
(c) Others, including hot cell facilities [Program Code(s): 21130, 21133]	753,000
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [Program Code(s): 23200]	[11] N/A
C. Licenses for possession and use of special nuclear material of less than a critical mass, as defined in § 70.4 of this chapter, in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.[15] [Program Code(s): 22140]	3,000
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A.[15] [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310]	8,600
E. Licenses or certificates for the operation of a uranium enrichment facility [Program Code(s): 21200]	3,340,000
F. Licenses for possession and use of special nuclear material greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities.[15] [Program Code: 22155]	6,400
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal. [Program Code: 11400]	1,590,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ recovery, heap-leaching, ore buying stations, ion-exchange facilities and in-processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode	
(a) Conventional and Heap Leach facilities [Program Code(s): 11100]	38,900
(b) Basic *In Situ* Recovery facilities [Program Code(s): 11500]	49,200
(c) Expanded *In Situ* Recovery facilities [Program Code(s): 11510]	55,700
(d) *In Situ* Recovery Resin facilities [Program Code(s): 11550]	[5] N/A
(e) Resin Toll Milling facilities [Program Code(s): 11555]	[5] N/A
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [Program Code(s): 11600, 12000]	[5] N/A
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [Program Code(s): 12010]	22,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees[1 2 3]
(5) Licenses that authorize the possession of source material related to removal of contaminants (source material) from drinking water [Program Code(s): 11820]	6,500
B. Licenses that authorize possession, use, and/or installation of source material for shielding.[16 17 18] [Program Code: 11210]	3,300
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. [Program Code: 11240]	5,500
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter [Program Code(s): 11230 and 11231]	6,400
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code: 11710]	8,000
F. All other source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810]	9,400
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution [Program Code(s): 03211, 03212, 03213]	30,500
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution [Program Code(s): 03214, 03215, 22135, 22162]	11,600
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when included on the same license. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 171.11(a)(1). [Program Code(s): 02500, 02511, 02513]	12,900
D. [Reserved]	[5] N/A
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units) [Program Code(s): 03510, 03520]	10,800
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03511]	11,800
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03521]	95,700
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03254, 03255, 03257]	11,800
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03250, 03251, 03252, 03253, 03256]	16,300
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03240, 03241, 03243]	4,600
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03242, 03244]	3,300
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	16,300
(1) Licenses of broad scope for possession and use of product material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–19. [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622]	25,900
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 20 or more. [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623]	32,700
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution [Program Code(s): 03620]	14,800
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C. [Program Code(s): 03219, 03225, 03226]	22,100
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license [Program Code(s): 03310, 03320]	27,000
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[19] [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03140, 03130, 03220, 03221, 03222, 03800, 03810, 22130]	9,300

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1] [2] [3]
Q. Registration of devices generally licensed under part 31 of this chapter	[13] N/A
R. Possession of items or products containing radium–226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section: [14]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4) or (5) but less than or equal to 10 times the number of items or limits specified [Program Code(s): 02700]	7,600
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5) [Program Code(s): 02710]	8,000
S. Licenses for production of accelerator-produced radionuclides [Program Code(s): 03210]	32,100
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material [Program Code(s): 03231, 03233, 03236, 06100, 06101]	[5] N/A
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material [Program Code(s): 03234]	20,800
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material [Program Code(s): 03232]	13,900
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies [Program Code(s): 03110, 03111, 03112]	16,000
B. Licenses for possession and use of byproduct material for field flooding tracer studies. [Program Code(s): 03113]	[5] N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material [Program Code(s): 03218]	38,500
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. [Program Code(s): 02300, 02310]	23,800
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] [Program Code(s): 02110]	33,800
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] [20] [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	14,700
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities [Program Code(s): 03710]	7,600
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	7,600
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	12,600
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	7,400
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	1,500
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers	
1. Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
2. Other Casks	[6] N/A
B. Quality assurance program approvals issued under part 71 of this chapter	
1. Users and Fabricators	[6] N/A
2. Users	[6] N/A
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)	[6] N/A
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects [Program Code(s): 25110]	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	[12] N/A

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1] [2] [3]
14. Decommissioning/Reclamation:	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs) [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200]	[7] N/A
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, whether or not the sites have been previously licensed	[7] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies [Program Code(s): 03614]	340,000
18. Department of Energy:	
A. Certificates of Compliance	[10] 1,514,000
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	616,000

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2015, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.,* human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the **Federal Register** for notice and comment.

[4] Other facilities include licenses for extraction of metals, heavy metals, and rare earths.

[5] There are no existing NRC licenses in these fee categories. If NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, 10 CFR parts 71 and 72 Certificates of Compliance and related Quality Assurance program approvals, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses under fee categories 7.B. or 7.C.

[10] This includes Certificates of Compliance issued to the U.S. Department of Energy that are not funded from the Nuclear Waste Fund.

[11] See § 171.15(c).

[12] See § 171.15(c).

[13] No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[15] Licensees paying annual fees under category 1.A., 1.B., and 1.E. are not subject to the annual fees for categories 1.C., 1.D., and 1.F. for sealed sources authorized in the license.

[16] Licensees subject to fees under categories 1.A., 1.B., 1.E., or 2.A. must pay the largest applicable fee and are not subject to additional fees listed in this table.

[17] Licensees paying fees under 3.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[18] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[19] Licensees paying fees under 3.N. are not subject to paying fees under 3.P. for calibration or leak testing services authorized on the same license.

[20] Licensees paying fees under 7.B. are not subject to paying fees under 7.C. for broad scope license licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

(e) The fee-relief adjustment allocated to annual fees includes the budgeted resources for the activities listed in paragraph (e)(1) of this section, plus the total budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section, as reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section for a given fiscal year, a negative fee-relief adjustment (or annual fee reduction) will be allocated to annual fees. The activities comprising the FY 2017 fee-relief adjustment are as follows:

* * * * *

■ 8. In § 171.19, revise paragraph (d) to read as follows:

§ 171.19 Payment.

* * * * *

(d) Annual fees of less than $100,000 must be paid as billed by the NRC. Materials license annual fees that are less than $100,000 are billed on the anniversary date of the license. The materials licensees that are billed on the anniversary date of the license are those covered by fee categories 1.C., 1.D., 1.F., and 2.A.(2) through 9.D.

* * * * *

Dated at Rockville, Maryland, this 15th day of June 2017.

For the Nuclear Regulatory Commission.

Maureen E. Wylie,

Chief Financial Officer.

[FR Doc. 2017–13520 Filed 6–29–17; 8:45 am]

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FEDERAL REGISTER

Vol. 82 Friday,
No. 125 June 30, 2017

Part VI

The President

Proclamation 9625—To Modify Duty-Free Treatment Under the Generalized System of Preferences and for Other Purposes

Federal Register
Vol. 82, No. 125
Friday, June 30, 2017

Presidential Documents

Title 3—

The President

Proclamation 9625 of June 29, 2017

To Modify Duty-Free Treatment Under the Generalized System of Preferences and for Other Purposes

By the President of the United States of America

A Proclamation

1. Pursuant to sections 501 and 503(a)(1)(A) of the Trade Act of 1974, as amended (the ''1974 Act'') (19 U.S.C. 2461 and 2463(a)(1)(A)), the President may, after receiving the advice of the United States International Trade Commission (the ''Commission''), designate certain articles as eligible for preferential tariff treatment under the Generalized System of Preferences (GSP) when they are imported from designated beneficiary developing countries.

2. Pursuant to sections 501, 503(a)(1)(A), and 503(b)(5) of the 1974 Act (19 U.S.C. 2463(b)(5)), and having received advice from the Commission in accordance with section 503(e) of the 1974 Act (19 U.S.C. 2463(e)), I have determined to designate certain articles as eligible articles when they are imported from beneficiary developing countries.

3. Pursuant to section 503(c)(1) of the 1974 Act (19 U.S.C. 2463(c)(1)), the President may withdraw, suspend, or limit application of the duty-free treatment accorded to specified articles under the GSP when imported from designated beneficiary developing countries.

4. Pursuant to section 503(c)(1) of the 1974 Act, and having considered the factors set forth in sections 501 and 502(c) of the 1974 Act (19 U.S.C. 2462(c)), I have determined to withdraw the application of duty-free treatment accorded to a certain article.

5. Section 503(c)(2)(A) of the 1974 Act (19 U.S.C. 2463(c)(2)(A)) subjects beneficiary developing countries, except those designated as least-developed beneficiary developing countries or beneficiary sub-Saharan African countries as provided in section 503(c)(2)(D) of the 1974 Act (19 U.S.C. 2463(c)(2)(D)), to competitive need limitations on the preferential treatment afforded to eligible articles under the GSP.

6. Pursuant to section 503(c)(2)(A) of the 1974 Act, I have determined that in 2016 certain beneficiary developing countries exported eligible articles in quantities exceeding the applicable competitive need limitations. I hereby terminate the duty-free treatment for such articles from such beneficiary developing countries.

7. Section 503(c)(2)(F)(i) of the 1974 Act (19 U.S.C. 2463(c)(2)(F)(i)) provides that the President may disregard the competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act (19 U.S.C. 2463(c)(2)(A)(i)(II)) with respect to any eligible article from any beneficiary developing country if the aggregate appraised value of the imports of any such article into the United States during the preceding calendar year does not exceed the amount set forth in section 503(c)(2)(F)(ii) of the 1974 Act (19 U.S.C. 2463(c)(2)(F)(ii)).

8. Pursuant to section 503(c)(2)(F)(i) of the 1974 Act, I have determined that the competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act should be disregarded with respect to certain eligible articles from certain beneficiary developing countries.

9. Section 503(d)(1) of the 1974 Act (19 U.S.C. 2463(d)(1)) provides that the President may waive the application of the competitive need limitations in section 503(c)(2) of the 1974 Act (19 U.S.C. 2463(c)(2)) with respect to any eligible article from any beneficiary developing country if certain conditions are met.

10. Pursuant to section 503(d)(1) of the 1974 Act, I have received the advice of the Commission on whether any industry in the United States is likely to be adversely affected by such waivers of the competitive need limitations provided in section 503(c)(2) of the 1974 Act. I have determined, based on that advice and the considerations described in sections 501 and 502(c) of the 1974 Act, and having given great weight to the considerations in section 503(d)(2) of the 1974 Act (19 U.S.C. 2463(d)(2)), that such waivers are in the national economic interest of the United States. Accordingly, I have determined that the competitive need limitations of section 503(c)(2) of the 1974 Act should be waived with respect to a certain eligible article from a certain beneficiary developing country.

11. Presidential Proclamation 8997 of June 27, 2013, suspended Bangladesh's designation as a beneficiary developing country for the purposes of the GSP. Presidential Proclamation 9333 of September 30, 2015, terminated Venezuela's designation as a beneficiary developing country for the purposes of the GSP. These proclamations made corresponding modifications to general note 4 of the Harmonized Tariff Schedule of the United States (HTS). Those modifications included technical errors, and I have determined that modifications to the HTS are necessary to correct them.

12. Presidential Proclamation 9466 of June 30, 2016, implemented the World Trade Organization Declaration on the Expansion of Trade in Information Technology Products (the ''Declaration'') and, pursuant to section 111(b) of the Uruguay Round Agreements Act (19 U.S.C. 3521(b)), modified the HTS to include the schedule of duty reductions necessary to carry out the Declaration. Those modifications included technical errors, and I have determined that modifications to the HTS are necessary to correct them.

13. Presidential Proclamation 8097 of December 29, 2006, implemented modifications to the HTS, pursuant to section 1206(a) of the Omnibus Trade and Competitiveness Act of 1988 (the ''1988 Act'') (19 U.S.C. 3006(a)), to include changes to the schedule considered necessary or appropriate by the Commission to accomplish the purposes of section 1205(a) of the 1988 Act (19 U.S.C. 3005(a)). Those modifications to the HTS were set out in Publication 3898 of the Commission, entitled ''Modifications to the Harmonized Tariff Schedule of the United States under Section 1206 of the Omnibus Trade and Competitiveness Act of 1988,'' which was incorporated by reference into Presidential Proclamation 8097. Annex I to that publication included a technical error, and I have determined that a modification to the HTS is necessary to correct it.

14. Presidential Proclamation 9549 of December 1, 2016, implemented modifications to the HTS, pursuant to section 1206(a) of the 1988 Act, to include changes to the schedule considered necessary or appropriate by the Commission to accomplish the purposes of section 1205(a) of the 1988 Act. Those modifications to the HTS were set out in Publication 4653 of the Commission, entitled ''Modifications to the Harmonized Tariff Schedule of the United States under Section 1206 of the Omnibus Trade and Competitiveness Act of 1988 and for Other Purposes,'' which was incorporated by reference into Presidential Proclamation 9549. Annex I to that publication included technical errors, and I have determined that modifications to the HTS are necessary to correct them.

15. Section 604 of the 1974 Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, and of other Acts affecting import treatment, and actions thereunder, including removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including title V and section 604 of the 1974 Act, do proclaim that:

(1) In order to designate certain articles as eligible articles when imported from a beneficiary developing country for purposes of the GSP, the Rates of Duty 1–Special subcolumn for the corresponding HTS subheadings is modified as set forth in section A of Annex I to this proclamation.

(2) In order to provide that one or more countries should no longer be treated as beneficiary developing countries with respect to one or more eligible articles for purposes of the GSP, the Rates of Duty 1–Special subcolumn for the corresponding HTS subheadings and general note 4(d) to the HTS are modified as set forth in sections B, C, and D of Annex I to this proclamation.

(3) The competitive need limitation provided in section 503(c)(2)(A)(i)(II) of the 1974 Act is disregarded with respect to the eligible articles in the HTS subheadings and to the beneficiary developing countries listed in Annex II to this proclamation, effective July 1, 2017.

(4) A waiver of the application of section 503(c)(2) of the 1974 Act shall apply to the article in the HTS subheading and to the beneficiary developing country set forth in Annex III to this proclamation, effective July 1, 2017.

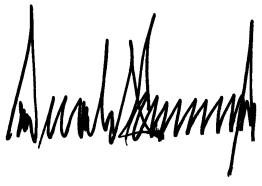
(5) In order to make technical corrections necessary to reflect the suspension of benefits under the GSP with respect to Bangladesh and the termination of benefits under the GSP with respect to Venezuela, the HTS is modified as set forth in Annex IV to this proclamation.

(6) In order to make technical corrections necessary to provide the intended tariff treatment to goods covered by the Declaration in accordance with Presidential Proclamation 9466 of June 30, 2016, and to certain goods as recommended in Publications 3898 and 4653 of the Commission, the HTS is modified as set forth in Annex V.

(7) The modifications to the HTS set forth in Annexes I, IV, and V to this proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the dates set forth in the relevant sections of Annexes I, IV, and V.

(8) Any provisions of previous proclamations and Executive Orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of June, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-first.



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ANNEX I

MODIFICATIONS TO THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

Section A.

Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after July 1, 2017, the Harmonized Tariff Schedule of the United States (HTS) is modified for the following subheadings:

For each of the following subheadings, the Rates of Duty 1-Special subcolumn is modified by deleting the symbol "A+" and inserting the symbol "A" in lieu thereof:

1104.19.90
2915.90.18
3301.13.00
3809.93.50
3912.20.00
4202.11.00
4202.12.21
4202.12.40
4202.12.81
4202.21.60
4202.21.90
4202.22.15
4202.22.45
4202.22.81
4202.31.60
4202.32.40
4202.32.80
4202.32.93
4202.32.99
4202.91.90
4202.92.15
4202.92.20
4202.92.31
4202.92.39
4202.92.45
4202.92.91
4202.92.97
4202.99.90

Section B.

Effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after July 1, 2017, the HTS is modified as provided herein, with the language in tabular format inserted in the HTS columns entitled "Heading/Subheading", "Article Description", "Rates of Duty 1-General", "Rates of Duty 1-Special", and "Rates of Duty 2", respectively.

Subheading 2922.49.40 is deleted and the following new provisions are inserted in lieu thereof:

[2922	:Oxygen-function...:]			
[	Amino-acids,. . .]	:	:	:
[2922.49	: Other:]	:	:	:
	: Other:]	:	:	:
	: "Amino-acids:	:	:	:
2922.49.43	: Glycine (Aminoacetic acid):.....	:4.2%	:Free (AU,BH,	:25%
	:	:	: CA,CL,CO,D,E,	:
	:	:	: IL,JO,KR,MA,MX,:	
	:	:	: OM,P,PA,PE,SG):	
2922.49.49	: . Other amino acids.....	:4.2%	:Free (A,AU,BH,	:25%"
	:	:	: CA,CL,CO,D,E,	:
	:	:	: IL,JO,K,KR,MA,	:
	:	:	: MX,OM,P,PA,	:
	:	:	: PE,SG)	:

Section C.

Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after July 1, 2017, general note 4(d) to the HTS is modified by adding, in numerical sequence, the following subheading numbers and the countries set out opposite such subheading numbers:

2933.99.22	India
6801.00.00	Turkey

Section D. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after July 1, 2017, the HTS is modified as provided in this section.

For each of the following subheadings, the Rates of Duty 1-Special subcolumn is modified by deleting the symbol "A" and inserting the symbol "A*" in lieu thereof:

2933.99.22
6801.00.00

ANNEX II

HTS Subheadings and Countries for Which the Competitive Need Limitation Provided in Section 503(c)(2)(A)(i)(II) Is Disregarded

0405.20.80	India	2912.49.10	India
0410.00.00	Indonesia	2913.00.50	India
0603.13.00	Thailand	2914.22.20	India
0710.80.50	Turkey	2914.31.00	India
0711.40.00	India	2914.40.10	Brazil
0713.34.40	Belize	2916.39.12	India
0713.60.10	India	2921.42.21	India
0713.60.60	India	2921.49.32	India
0714.50.60	Ecuador	2922.29.26	India
0802.31.00	Moldova	2922.50.19	India
0802.52.00	Turkey	2924.29.36	India
0802.80.10	India	2924.29.43	India
0810.60.00	Thailand	2926.10.00	Brazil
0813.40.10	Thailand	2930.90.30	India
0813.40.80	Thailand	2932.20.25	India
1103.19.14	India	2932.99.08	India
1601.00.40	Brazil	2933.99.06	India
1604.19.81	Philippines	2935.00.06	India
1605.58.55	Indonesia	3802.90.10	Brazil
1701.91.10	Brazil	3808.50.10	India
2001.90.45	India	3808.93.20	India
2004.90.10	Ecuador	3824.90.31	Brazil
2005.80.00	Thailand	3824.90.32	Brazil
2006.00.70	Thailand	3920.94.00	India
2008.99.50	Thailand	4101.90.35	India
2306.50.00	Papua New Guinea	4101.90.50	Brazil
2401.10.95	Brazil	4104.11.30	India
2516.20.20	India	4106.21.90	India
2813.90.50	India	4106.22.00	Pakistan
2827.39.25	India	4107.11.40	India
2827.39.45	India	4107.11.60	Turkey
2828.10.00	India	4107.12.40	India
2831.90.00	India	4107.19.40	India
2833.29.40	Turkey	4107.91.40	India
2834.10.10	India	4107.92.40	India
2840.11.00	Turkey	4107.99.40	India
2841.61.00	India	4107.99.80	Brazil
2841.70.50	India	4202.22.35	India
2844.30.10	India	4302.20.60	Brazil
2904.10.08	India	4601.22.40	Indonesia
2905.19.10	Brazil	4602.19.23	Philippines
2905.49.10	India	5208.41.20	India
2906.19.30	Brazil	5209.41.30	India
2907.12.00	India	5607.90.35	Philippines
2907.15.10	India	5702.92.10	India
2907.29.25	India	7113.20.25	India
2909.11.00	India	8112.19.00	Kazakhstan
2909.30.10	India	8516.90.85	Turkey
2910.10.00	India	9205.90.14	India
2910.20.00	Brazil	9614.00.26	Egypt

ANNEX III

HTS Subheadings and Countries Granted a Waiver of the Application of Section 503(c)(2)(A) of the 1974 Act

4409.10.05	Brazil

ANNEX IV

Section A. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 2017, general note 4(d) to HTS is modified by removing, in numerical sequence, the following subheading numbers and the countries set out opposite such subheading numbers:

0306.33.20	Venezuela
0306.93.20	Venezuela

Section B. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 2017, the HTS is modified as provided in this section.

For each of the following subheadings, the rates of Duty 1-Special subcolumn is modified by deleting the symbol "A*" and inserting the symbol "A" in lieu thereof:

0306.33.20
0306.93.20

Section C. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after September 3, 2013 general note 4(a) is modified to remove Bangladesh as a currently qualifying member country of the South Asian Association for Regional Cooperation (SAARC)

ANNEX V

Section A. Effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after July 1, 2016, subheading 8529.90.95 is hereby modified by inserting, in the Rates of Duty 1-Special subcolumn of column 1 in the parenthetical expression following the "Free" rate of duty, the symbol "C,".

Section B. Effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after January 1, 2007, note 9(b)ii to Chapter 85 is modified by deleting "of" and by inserting in lieu thereof "or" to read as follows: "Hybrid integrated circuits in which passive elements (resistors, capacitors, inductances, etc.), obtained by thin- or thick-film technology, and active elements (diodes, transistors, monolithic integrated circuits, etc.), obtained by semiconductor technology, are combined to all intents and purposes indivisibly, by interconnections or interconnecting cables, on a single insulating substrate (glass, ceramic, etc.). These circuits may also include discrete components;".

Section C. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after July 1, 2016, general note 4(d) to the HTS is modified by removing, in numerical sequence, the following subheading number and the country set out opposite such subheading numbers:

8528.71.10	India

Section D. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 2017, general note 4(d) to the HTS is modified by

1. adding, in numerical sequence, the following subheading number and the country set out opposite such subheading number:

2202.99.36	Philippines

2. removing, in numerical sequence, the following subheading number and the country set out opposite such subheading number:

2202.90.36	Philippines

[FR Doc. 2017–14063

Filed 6–29–17; 2:00 pm]

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